78-1118

IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 1118

PETER H. FORSHAM, ET AL.,
Plaintiff-Petitioners,

v.

JOSEPH A. CALIFANO, JR., ET AL.,
Defendant-Respondents.

On Writ of Certiorari to the United States Court of Appeals For the District of Columbia Circuit

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BRIEF FOR PLAINTIFF-PETITIONERS

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CITATIONS TO OPINIONS BELOW

The Opinion of the Court, Concurring Opinion and Dissenting Opinion of the United States Court of Appeals for the District of Columbia Circuit are not officially reported and are set out in the Appendix at pp. 217, 238, and 240 respectively. The unreported Statement of Circuit Judge Bazelon as to why he voted for rehearing is set out in the Appendix at p. 259. The Order of the United States District Court for the Dis-

trict of Columbia granting respondents' Motion to Dismiss is set out in the Appendix at p. 180.

JURISDICTION

The Judgment of the United States Court of Appeals for the District of Columbia Circuit was entered on July 11, 1978. The Petition for Rehearing and the Suggestion for Rehearing En Banc were denied on October 17, 1978. Jurisdiction of this Court was invoked under 28 U.S.C. § 1254(1) to review the decision of the United States Court of Appeals for the District of Columbia Circuit by Petition for a Writ of Certiorari filed January 15, 1979. The Petition for a Writ of Certiorari was granted by this Court on May 14, 1979.

QUESTIONS PRESENTED

1. Whether records derived from a scientific study funded entirely by an agency of the federal government which was also significantly involved in the planning, implementation, and monitoring of the study constitute "agency records" under 5 U.S.C. § 552.

2. Whether records of government funded research which, by contract and regulation, are fully available for government access and have in fact been partially audited by and at the direction of the government, are "agency records" under 5 U.S.C. § 552.

3. Whether records of government funded research which have been absorbed into the decision-making process of a government agency, and form the basis for its regulatory action, are "agency records" under 5 U.S.C. § 552.

STATUTES AND REGULATIONS INVOLVED

This is an action brought under the Federal Freedom of Information Act (FOIA), 5 U.S.C. § 552, to order the production of agency records improperly withheld. Also directly pertinent to this action and the records sought are certain United States Department of Health, Education, and Welfare regulations governing the administration of grant research and the Federal Food and Drug Administration regulations governing the maintenance and disclosure of records. The statute and regulations are set forth, in pertinent part, in the appendix to plaintiff-petitioners' brief.*

STATEMENT OF FACTS

Introduction

Plaintiff-petitioners (hereinafter petitioners) are three physicians who are members of the Committee on the Care of the Diabetic (CCD), an association of more than 200 physicians throughout the United States who are involved in the daily management and treatment of patients suffering from adult-onset diabetes mellitus, a disease affecting millions of Americans. Petitioners, and substantial numbers of the CCD members they represent, are active medical practitioners and leading researchers and educators in the field of diabetology.

At issue is petitioners' right of access under the Freedom of Information Act (FOIA) to identifiable collected data generated in the course of a unique scientific study known as the University Group Diabetes Pro-

* Three years have elapsed since the Appendix was prepared for the proceedings below. In order to provide the Court updated scientific, administrative and regulatory information, a separate appendix is included at the conclusion of plaintiff-petitioners' brief (hereinafter cited as App. Br.).

gram (UGDP). Subsumed within the legal issue is a fundamental scientific concern; that is, that scientific inquiry and the scientific method depend upon peer access to and analysis of a study's underlying data whenever legitimate scientific controversy arises over the study's reported findings. Only through such access and analysis can the study's validity or lack thereof be determined.[1]

The University Group Diabetes Program

The UGDP is a collaborative effort involving twelve diabetes clinics around the country and a computerized Coordinating Center at the University of Maryland. It was originally formed in 1959 as a result of a two-year planning grant from the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD). Beginning in 1961 and continuing to 1978, the UGDP was awarded a series of NIAMDD grants totalling approximately fifteen million dollars, the purpose of which was to study the effectiveness of four different treatment regimens[2] in preventing the principal complications of diabetes mellitus.[3] NIAMDD grants constituted the sole source of UGDP funding.

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[1] A recent perspective of the UGDP study, its design, goals and controversial history has appeared in SCIENCE, the Journal of the American Association for the Advancement of Science. "Controversy Over Study of Diabetes Drugs Continues For Nearly A Decade," 203 SCIENCE 986 (1979). The text of this article is reproduced in App. Br. 1a.

[2] The four regimens were: diet (plus placebo) alone, diet plus a fixed dose of an oral hypoglycemic drug (tolbutamide), diet plus insulin in a fixed dosage, and diet plus insulin in a variable dosage. A fifth schedule was subsequently added involving diet plus a fixed dosage of phenformin, another type of oral hypoglycemic drug.

[3] The principal complications are cardiovascular disease, retinopathy, nephropathy and neuropathy.

More than one thousand patients were enrolled, treated, and followed at the twelve clinics, using a system of double blind controls, i.e., neither patient nor physician knew which particular regimen the patient was receiving. To assess the relative efficacy of the treatments under investigation, the results of the various tests administered at the beginning of the study and on a quarterly basis thereafter were recorded onto standardized forms and forwarded from each of the clinical centers to the UGDP Coordinating Center at the University of Maryland. There, they were collected, coded, keypunched, and transferred onto magnetic discs and tapes to permit rapid computer access and analysis. It is these standardized reporting forms, in their original form and as processed for computer purposes by the Coordinating Center, that constitute the UGDP raw data sought here.

NIAMDD maintained a direct and close involvement with the UGDP as the study progressed. In addition to reviewing and approving UGDP progress reports on a regular basis and awarding UGDP renewal funding annually, NIAMDD established a number of special mechanisms for monitoring and directing the course of the UGDP as it developed. Employees of NIAMDD actively participated in these activities. See pp. 32 to 34 *infra*.

Starting in 1968, the FDA established direct contact with the UGDP, particularly after early data analyses at the Coordinating Center suggested the statistical possibility of an excess mortality in patients assigned to the drug tolbutamide as compared to the other study regimens. The FDA's Medical Advisory Board recom-

mended that the agency "review the raw data and continue in close contact with the UGDP."[4]

However, no agency review of the raw data took place and, in the Spring of 1970, the FDA received from the UGDP an advance copy of its report. The principal conclusion of the report was that the combination of diet and oral hypoglycemic medication was no more effective than diet alone in prolonging life, and that there was a possible correlation between oral medication and cardiovascular mortality.[5] To evaluate the report, the FDA convened an *ad hoc* committee consisting of FDA staff, UGDP investigators, and five outside consultants who were specialists in the treatment of diabetes. At their meeting, held on May 21, 1970, the consultants had serious reservations about the study and refused to endorse it.[6] Nonetheless, even before the meeting had adjourned, articles announcing the UGDP conclusions appeared in the lay press.[7]

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[4] Oversight Hearings Before the Subcommittee on Intergovernmental Regulations of the House Committee on Government Operations, 91st Congress, 2nd Session (Statement of Charles C. Edwards, M.D., Commissioner of Food and Drugs, at 15) (June 9, 1970).

[5] The formal publication of the report first appeared in November of 1970. Klimt, Knatterud, Meinert & Prout, "The University Group Diabetes Program: A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients With Adult-Onset Diabetes," 19 DIABETES 747 (Supp. 2) (1970).

[6] "Controversy Over Study of Diabetes Drugs Continues For Nearly a Decade," 203 SCIENCE 986, 987 (1979) (See App. Br. 4a).

[7] See, e.g., "Diabetes Pills—A Killer?," New York Post, May 21, 1970; "Anti-Diabetes Pills Held Causing Earlier Death," The Washington Post, May 21, 1970.

Press accounts of the UGDP conclusions triggered immediate and grave concern on the part of diabetic patients and their physicians who knew little about the UGDP. Professional conferences were convened, scientific articles were published and additional studies, albeit of a more limited scope, were undertaken in the hopes of evaluating the UGDP conclusions and determining their validity. Rather quickly, the dialogue turned into a debate with the medical and scientific communities sharply divided along pro- and anti-UGDP lines. Supporters of the UGDP pointed to the study's cost, duration, broad patient base, and sophisticated design to confirm the validity of the findings.[8] UGDP critics, on the other hand, cited numerous inadequacies in study design, methodology, and execution, not the least of which was an apparent breakdown in initial randomization which led to a far greater predisposition to cardiovascular risk in hypoglycemic-treated subjects than in control group subjects.[9]

The scientific debate took on an added dimension when Dr. Angela Bowen, a UGDP investigator, challenged the integrity of the study's data base and re-

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[8] For example:

Cornfield, "The University Group Diabetes Program: A Further Statistical Analysis Of The Mortality Findings," 217 JAMA 1676 (1971).

Prout, Knatterud, Meinert, et al., "The UGDP Controversy: Clinical Trials Versus Clinical Impressions," 21 DIABETES 1035 (1972).

[9] For example:

Feinstein, "Clinical Biostatistics: VIII. An Analytical Appraisal Of The University Group Diabetes Program (UGDP) study," 12 CLINICAL PHARMACOLOGY 167 (1971);

Schor, "The University Group Diabetes Program: A Statistician Looks At The Mortality Results." 217 JAMA 1671 (1971).

signed from the study when her request to examine the raw data was denied.[10] Since all data analyses had been conducted at the Coordinating Center under the direction of defendant-respondent Christian R. Klimt, and since all UGDP reports had been prepared at the

[10] Dr. Bowen testified as follows before FDA at the public hearings on the proposed labeling change for oral hypoglycemic drugs on August 20, 1975:

> An even more troublesome aspect has not been as well explored. This involves the matter of personal integrity and scientific honesty of one key member of the group. This question was actively considered both privately and openly among the investigators as early as 1968. It has also been asked publicly since that time. The question that the FDA must now ask and hopefully answer is "Were the data that were gathered in the field accurately and honestly recorded and reported from the coordinating center in Baltimore?" I fully recognize that this is a serious allegation but there is basis for reasonable doubt. You will recall that this was a double blind study. Investigators did not know what medication a patient was taking. Data were simply recorded and sent along to the biostatistician at the coordinating center. We then received a printout of the cumulative results. Therefore if one was told that a given death or other side effect occurred in a tolbutamide patient it was taken on faith because the investigator never knew for sure. [Tolbutamide is an oral hypoglycemic drug and a competitor of phenformin.] It did not occur to me to question this state of affairs until 1968 when the first allegation was made that the death rate was higher in the tolbutamide group. At the same meeting another investigator revealed that the biostatistician, Dr. Klimt, was a paid consultant to U.S. Vitamin, the then makers of phenformin. This was at first denied, then acknowledged. A spirited discussion followed during which the potential for abuse under such circumstances was discussed at length. This ended with the demand from the New York delegation that an independent review of the data be undertaken by outside statisticians. Dr. Klimt threatened to resign if this was done. This threat did not meet with universal disapproval, but a compromise was finally reached in which a review would be done but Dr. Klimt would be permitted to choose the reviewers! Drs. Cornfield and Brown were his choices. It is my understanding that they simply reviewed the numbers and methods sent to them by the coordinating center and that raw data were not used even then. This episode caused a rift of major proportions among the investigators. (A. 153-154)

Center, this challenge to the Coordinating Center and the raw data went directly to the validity of the UGDP's reported findings.

FDA's Adoption of the UGDP

From May 1970, despite the absence of any medical or scientific consensus regarding the UGDP, the FDA began issuing Reports and Drug Information Bulletins to physicians around the country, setting forth the agency's revised position on the proper treatment of diabetes.[11] This action was based entirely on the UGDP.

CCD was organized immediately thereafter in an attempt to assure that both diabetic patients and their physicians were provided with full, accurate, and truthful information concerning the safety and efficacy of the various treatment modalities. Petitioners became concerned that such premature FDA recommendations had created needless anxiety for diabetics and confusion for their physicians. In a December 1, 1970 telegram to the FDA entitled a "Statement on the Treatment of Diabetes," petitioners stated that physicians had been provided no basis for making their own assessment of the validity of the UGDP and requested that

> before any further action is taken by regulatory agencies, the [UGDP] raw data should be made available to the scientific community at large (A. 7).

In a subsequent exchange of correspondence with FDA, petitioners renewed their request for an inde-

[11] Much of the early history of FDA's adoption of the UGDP is related in 40 Fed. Reg. 28589 (1975).

pendent review of the raw data. Nevertheless, the FDA endorsed the UGDP findings based on an allegedly full and careful evaluation of the study without responding directly to petitioners' request.[12]

Shortly thereafter, the FDA proposed relabeling of all oral hypoglycemic drugs to reflect UGDP conclusions. Petitioners formally petitioned the FDA to rescind its proposal and to withhold further action pending independent corroboration of the study. In their petition, petitioners presented a detailed critique of UGDP conclusions and again requested access to the raw data both for themselves and for other qualified researchers:

> The failure to release the basic data and patient records so long sought by the scientific community has made it impossible to draw final conclusions about the study and the purpose of this critique is to raise the questions precipitated by the data which has been released. CCD Petition to FDA (October 7, 1971).

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[12] The unavailability of the raw data was a pivotal factor in the icy reception the UGDP results received abroad when they were published. The following scenario is described when Dr. Klimt first presented the UGDP findings to the German Diabetes Association in Dusseldorf, West Germany in 1970:

> The burden of presentation of the UGDP viewpoint fell mainly on Dr. Klimt. The members of the German host group kept raising pertinent questions to which, apparently, they did not have adequate responses. Thereupon, a spokesman for the German group said, "We're asking you a simple question: if we ask for access to the raw data in Baltimore can we see it?" To this Dr. Klimt responded, "No!"

As a result, the UGDP was not endorsed by the German, Canadian, British, or Swedish Governments.

Cooper, "The Use of Outside Advisory Sources in Regulatory Decision-Making on Drugs", p. VI-8, (1971) (published by the Interdisciplinary Communications Program, Smithsonian Institution, March 1971).

FDA denied the petition on June 5, 1972, and again fully endorsed the UGDP. In response to petitioners' request for access to the raw data, the FDA responded:

> Your petition states that the results of the UGDP study are not available and therefore not subject to the usual critical review. *We have been assured that the UGDP personnel will honor any reasonable request for data and information.* Letter from Charles C. Edwards, M.D., FDA Commissioner, to Neil L. Chayet (June 5, 1972) (emphasis supplied).

However, personnel at the Coordinating Center were not responsive to requests for access to the raw data, even from investigators associated with the UGDP (A. 155). Consequently, when the FDA reinitiated its attempts to require relabeling of oral hypoglycemic drugs based solely on the UGDP, petitioners brought an action in the United States District Court for the District of Massachusetts to enjoin such relabeling and to require production of the raw data. *Bradley* v. *Richardson* (72-2517-M, 1972). A preliminary injunction issued enjoining the proposed relabeling, from which order the FDA appealed. In its opinion on July 31, 1973, the First Circuit Court of Appeals remanded the labeling question to the FDA while discussing, in *dicta,* petitioners' entitlement to the raw data as being part of the administrative record. *Bradley* v. *Weinberger,* 483 F.2d 410, 414 note 4 (1st Cir. 1973).

The Biometric Report

At this point, the FDA deferred regulatory action on the oral hypoglycemics pending a report from a group of outside biostatisticians known as the Bio-

metric Society (Biometrics). At the request of and under contract with NIAMDD, Biometrics reviewed the statistical, as opposed to clinical, quality of the UGDP. It had been "urged" by NIAMDD

> to utilize all the resources it need[ed] to arrive at a satisfactory answer . . . Although no prior approval by the NIH is required, we shall expect to be kept informed of the conclusions as they develop.[13]

The fact that the Biometics Report did not issue for two and one-half years contributed to rumors of sharp division among its members along familiar pro- and anti-UGDP lines. Petitioners were informed that Biometrics had actually prepared an earlier draft of its report which NIAMDD opposed due to its criticism of the Institute sponsored study. The final Biometric Report endorsed many of the arguments on both sides of the controversy and concluded with "moderately strong" support for the UGDP.[14]

Particularly relevant for purposes of this action is that, by contract with NIAMDD, Biometrics was given direct access to *all* of the UGDP raw data in the course of preparing its Report. While Biometrics actually reviewed only portions of the available data, this was a self-imposed limitation which, to many, diminished the ultimate value of the Report.[15] With the Biometrics findings in hand, the FDA once again proposed relabeling of the oral hypoglycemics.[16]

[13] Letter from Robert Q. Marston, Director of NIH, to Colin White, Committee Chairman, June 9, 1972, quoted in "Report of the Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents", 231 JAMA 583, 585 (1975) (hereinafter Biometric Report).

[14] *Id* at 599.

FOIA Requests

Since the FDA resumed regulatory action based on the Biometrics Report, a report prepared following direct access to the raw data, petitioners initiated a series of FOIA requests for the same access to the raw data and for a copy of the draft Biometrics Report. These requests were directed to the various agencies within HEW which had been involved with the UGDP. The correspondence back and forth consumed a period of seven months:

- Request of October 14, 1974 to NIAMDD; Denied on October 21, 1974 (A. 40-41);
- Request of November 4, 1974 to FDA (A. 42); Forwarded to the Public Health Service on November 11, 1974 (A. 44-45);

  Forwarded from the Public Health Service back to NIAMDD on November 22, 1974 (A. 46);

  Forwarded to HEW and denied on December 3, 1974 (A. 47-48);
- Request of January 2, 1975 to HEW for administrative review and reconsideration; No Action re UGDP data (A. 49-54);
- Request renewed on May 6, 1975; Denied on May 23, 1975 (A. 55-58).

[15] For example: Bradley, "Settling the UGDP Controversy?" 232 JAMA 813 (1975); O'Sullivan, "Decisive Factors in the Tolbutamide Controversy," 232 JAMA 825 (1975).

[16] 40 Fed. Reg. 28582 (1975).

Finally on August 7, 1975, following an exchange of further correspondence, the Assistant Secretary for Health of HEW, Dr. Theodore Cooper, notified petitioners of the following:

- That neither the UGDP sponsor (NIAMDD) nor the agency proposing regulatory action based on the UGDP (FDA) had ever reviewed or even seen the raw data;
- That FDA's proposed relabeling action was based solely on the published reports of the UGDP and not on its own analysis of the data;
- That the raw data were now secured in a Maryland bank vault under the control of Dr. Klimt and;
- That, in HEW's view, such data were the property of the Coordinating Center and the UGDP investigators and that HEW had no authority to require the data to be made available in any form other than published reports (A. 68-69).

Immediately upon receipt of this statement, petitioners notified HEW of their intention to seek judicial relief, having exhausted administrative remedies (A. 70-71).

District Court Proceedings

On September 30, 1975, petitioners filed a complaint under the FOIA seeking production of the UGDP raw data and the draft Biometrics Report. The complaint also sought a judgment that the withholding of the requested records by both the federal respondents and respondent Klimt was unlawful (A. 3). Accompanying the complaint were affidavits of the petitioners (A. 12-16) documenting the scientific controversy surrounding the UGDP study, the efforts petitioners had taken to discover the scientific facts of the matter, and the importance of the raw data to those efforts. Also appended were exhibits chronicling the exchange of communications with the federal respondents (A. 18-95, 111-114).

On November 21, 1975, the federal respondents moved for dismissal and/or summary judgment. Accompanying their pleadings were affidavits of the Assistant Secretary for Health for HEW and the Director of NIAMDD which stated that no officer or employee within HEW or its sub-agencies had ever seen the raw data and that in their judgment, such data were not agency records under the provisions of FOIA (A. 140-148).

Respondent Klimt filed separate pleadings, moving to dismiss petitioners' complaint and to quash service of process on the grounds of lack of jurisdiction over the person and insufficiency of process (A. 116). Petitioners opposed the motions of respondent Klimt (A. 118), and filed an opposition to the motions of the federal respondents while moving for summary judgment and hearing (A. 151).

On December 16, 1975, FDA announced its intention to audit the UGDP raw data (New York Times, December 17, 1975), a fact of which petitioners asked the District Court to take judicial notice during the course of oral argument.

On February 5, 1976, the Court dismissed petitioners' complaint for FOIA relief against the federal re-

spondents and granted federal respondents' motion to dismiss, ruling that:

(1) no official or employee of HEW, NIH, FDA, or NIAMDD had ever been in possession of the UGDP raw data;

(2) the raw data were the property of the individual investigators and UGDP study Coordinating Center and remained in the possession, custody and control of the UGDP study Coordinating Center;

(3) neither the individual investigators nor the UGDP study Coordinating Center was an "agency" under FOIA;

(4) consequently, the raw data in issue were not "agency records" subject to FOIA (A. 180).

On February 25, 1976, petitioners appealed the denial of FOIA relief to the United States Court of Appeals for the District of Columbia. At oral argument before the Court of Appeals on December 2, 1976, counsel for federal respondents confirmed that the FDA had undertaken an audit of the UGDP raw data and that all materials gathered during the course of the audit would be provided to petitioners in response to their FOIA requests.

When no audit materials were forthcoming, petitioners once again filed a formal FOIA request with the FDA.[17] After a five-month exchange of correspondence,[18] petitioners received a set of documents purporting to represent all the UGDP documents that had come into the FDA's possession during the course of the UGDP audit. Acknowledging in advance that the documents were "not as informative as you might like," [19] the FDA stated that instead of having the raw data copied and forwarded to the agency for audit, it had performed the audit by going out to the Coordinating Center, reviewing the raw data on-site, selecting portions of the data for abstracting, and even smaller portions for copying and transmittal back to the FDA. All that the FDA provided petitioners in fulfillment of its pledge at oral argument were the few UGDP documents which had been selected for copying and physical transfer to the FDA.

[17] Letter from Neil L. Chayet to J. Richard Crout, M.D., Director of FDA Bureau of Drugs (January 5, 1977).

[18] Letter from J. Richard Crout, M.D., Director of FDA Bureau of Drugs to Neil L. Chayet (February 9, 1977); Letter from Neil L. Chayet to Donald Kennedy, FDA Commissioner (May 5, 1977); Letter from Mark A. Elengold of FDA's Information Office to Neil L. Chayet (May 20, 1977). The text of these letters is set out in App. Br. 19a to 24a.

[19] Letter from J. Richard Crout, M.D., Director of FDA Bureau of Drugs to Neil L. Chayet (February 9, 1977), App. Br. 19a.

Suspension of Phenformin Pending FOIA Appeal

On July 25, 1977, while the FOIA appeal was pending, HEW suspended the New Drug Application for phenformin, an oral hypoglycemic medication and one of the drugs studied by the UGDP, as an "imminent hazard to public health." [20] This was the first time the provisions of 21 U.S.C. § 355(e) had ever been invoked in this manner. In his Order suspending the drug, Secretary Califano stated that HEW placed a primary reliance on the UGDP data and the FDA's endorsement of the study.[21]

[20] In re: New Drug Applications for Phenformin, Order of the Secretary Suspending Approval (July 25, 1977).

[21] *Id.* at 38.

The full administrative hearing on the suspension order reached the oral testimony phase on October 4, 1977. Prior to that time all participants at the hearing, including FDA, had executed a statement required by regulation (21 C.F.R. § 12.85) that they had submitted for the administrative record all data in their files relevant to the case and, beyond that, all data upon which they relied for purposes of the hearing. Neither the UGDP raw data nor the audit findings were included in FDA's submission. Only a copy of the published UGDP reports was submitted.

Petitioners, who participated at the phenformin hearing, objected to FDA's omission of the UGDP raw data, and the Administrative Law Judge ordered FDA to come forward with all UGDP data in their possession.[22] On October 6, 1977, the next to the last day of the phenformin hearings, FDA presented the participants with several thousand pages of data gained through the FDA audit of the UGDP. FDA acknowledged that these materials did not include all raw data reviewed by FDA personnel at the Coordinating Center, but simply those limited portions of the raw data that had been copied, abstracted, or directly transferred to government premises. FDA further stated that the audit report was in its final draft stages but not ready for submission.

On February 6, 1978, the Administrative Law Judge issued his decision upholding the HEW suspension

[22] In the Matter of the Proposal to Withdraw Approval of the New Drug Application for Phenformin Hydrochloride (FDA Docket No. 77N-0150), Hearing Transcript at 143 (October 5, 1977).

order. In so doing, the Judge acknowledged considerable problems with the FDA's reliance on the UGDP:

> Although certain underlying [UGDP] data was made available during the hearing, it was admittedly incomplete. The lack of availability of underlying data casts considerable doubt on the reliability of the UGDP conclusions from an evidentiary standpoint. To the extent such data was not made available, the UGDP conclusions cannot be considered as substantiated on this record.[23]

Nonetheless, the Judge proceeded over petitioners' objections to permit the UGDP to be used in support of the agency's position on phenformin. The stated reason for this action was that no participant had provided the Judge with a "specific analysis" of the "precise extent" to which the UGDP data were faulty.[24] Since such an analysis would have required review of all of the raw data, petitioners were confronted with a "Catch-22" result.[25]

[23] In the Matter of the Proposal to Withdraw Approval of the New Drug Applications for Phenformin Hydrochloride (FDA Docket No. 77N-0150), Initial Decision of Administrative Law Judge Daniel J. Davidson at 7 (February 6, 1978).

[24] *Id.*

[25] It should be pointed out that even on the basis of the very limited portions of the raw data turned over by the FDA on the last day of the phenformin hearings, CCD was able to prepare an analysis which cast serious doubt on the validity of the study, particularly as applied to the suspension action. This analysis was submitted for the administrative record. However, it was not until the FDA released its UGDP audit report more than a year later, that the FDA first acknowledged the accuracy of CCD's analysis.

> We agree with CCD that this patient probably should not have been a candidate for phenformin therapy . . . *However it is not the purpose of this audit to pass judgment on the propriety of details of the UGDP study but rather to assess its validity.*

Decisions of Court of Appeals

On July 25, 1978, the Court of Appeals issued its Opinion that the UGDP raw data were not "agency records" under the FOIA. Speaking for the majority, Judge Leventhal defined the test of "agency records" in terms of whether an agency had "created" or "obtained" those records in the course of doing its work (A. 232). Further interpreting the test, Judge Leventhal stated that where records are created by a private entity, the applicability of FOIA will turn on whether the government is involved in the "core planning or execution of the program" (A. 232).

In his dissenting opinion, Judge Bazelon stated that the UGDP data were "agency records" under the FOIA, since the government had been "significantly involved" in the study in terms of funding, access to the raw data, and reliance on the study as the basis for regulatory action.

On July 25, 1978, petitioners filed a Motion for Rehearing and Suggestion for Rehearing En Banc, citing in particular the extensive government involvement in the core planning and execution of the UGDP which met the test established by the majority opinion (A. 261). The motion was denied on October 17, 1978, with

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The Food and Drug Administration Audit of the University Group Diabetes Project, Appendix K at 4 (October 16, 1978) (emphasis supplied).

Since the patient referred to was one of only three UGDP-reported cases of adverse reaction to phenformin and the *only* phenformin mortality, the above concession by the FDA undermined the entire basis for its suspension action of one year before, at least insofar as the action was based on the UGDP study.

Judge Bazelon voting for rehearing on the basis of petitioners'

> strong case that, from the inception of the study, the government involvement in planning and execution has been pervasive (A. 259).

Developments Since the Court of Appeals Decisions

Nearly three years after the FDA audit was announced, the FDA published in the Federal Register of November 14, 1978 a notice of public availability of its audit report, 43 Fed. Reg. 52732 (1978). The report acknowledged "errors and discrepancies" between the UGDP raw data and the published reports but found that none appeared to be of "sufficient frequency or magnitude to invalidate" UGDP findings.[26] At the same time, FDA reissued its 1975 proposed regulations relabeling the oral hypoglycemic drugs, 40 Fed. Reg. 28587 (1975).

By FDA design, the scope of the audit was limited and excluded review of the clinical course and judgments critical to determining the validity of the raw data. Publication of the restricted FDA audit, far from ending the UGDP controversy, predictably led to its further escalation.

- One of the UGDP's own investigators, Dr. Charles Kilo, termed the UGDP a "Medical Watergate"[27] and urged the FDA not to take further action based on the UGDP. His conclusion was based on his own analysis of portions of the UGDP raw data, which had been made avail-

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[26] The Food and Drug Administration Audit of the University Group Diabetes Project, at 2 (October 16, 1978).

[27] "Sugar Coated Audit," Barron's (January 15, 1979) at 9.

able to him by some of the clinical centers after the Coordinating Center had denied him access to the complete raw data.

- A former Commissioner of the FDA, Dr. Charles C. Edwards, admitted that his agency had erred when it adopted the UGDP report in 1970 and called for HEW, FDA, and other government agencies to recognize that they had assumed a "partisan position" in the matter and that the principle of checks and balances required them not to proceed as "participant, policeman, prosecutor, judge, jury, and Supreme Court." [28]
- *Science*, the prestigious voice of the American Association for the Advancement of Science, published an updated analysis of the UGDP controversy, indicating serious scientific opinion moving away from continued endorsement of the study.[29]
- The American Medical Association requested its Council on Scientific Affairs to reassess its former position in support of the UGDP in light of recent developments.[30]
- The American Diabetes Association called for total "reappraisal" of the UGDP data, suggesting that UGDP published reports required restudy and modification because prior reviews of

[28] Interview with Charles C. Edwards, M.D., Medical Tribune (January 17, 1979) at 6.

[29] See note 6 *supra*.

[30] Telegram from American Medical Association Executive Vice-President James H. Sammons, M.D., to HEW Secretary Joseph Califano, the National Institutes of Health, The American College of Physicians, the American Association of Family Practice, the American Society of Internal Medicine, and the U.S. Surgeon General (February 2, 1979).

the UGDP raw data had been inadequate. While questioning the logistical feasibility of performing a new review, the ADA stated as follows:

> The unique nature and size of the UGDP study, its multi-centered base, the time now elapsed from the inception of the study, and the previously proposed governmental decisions concerning the nature of professional advice that physicians should give their diabetic patients suggest . . . that access to and review of data from the twelve centers of the UGDP should be carried out by ad-hoc review groups.[31]

On the basis of these and thousands of other comments from the public, the FDA announced an extension of time for its proposed relabeling of the oral hypoglycemic drugs, first until March 16, 1979, and then until July 16, 1979.[32]

SUMMARY OF ARGUMENT

In the Argument that follows, petitioners demonstrate that the UGDP raw data constitute "agency records" under the FOIA and are subject to disclosure to petitioners and other members of the public. Disclosure is required as a matter of law because the government was significantly involved in the UGDP, through total funding of and core participation in the design, implementation and policy direction of the study. Further, the government had unrestricted rights of access to all of the UGDP raw data by virtue of its contractual and

[31] American Diabetes Association, "A Statement on the UGDP Controversy" (January 12, 1979) at 4-5.

[32] 44 Fed. Reg. 17720 (1979).

regulatory relationship with the UGDP. Having invoked these rights on at least two occasions to sponsor and conduct audits of selective portions of the data, the government asserted control over the data as a whole. Further, the government absorbed the UGDP data into the regulatory process by relying upon the data for purposes of regulatory decision making. Such reliance brought the data squarely within the information base upon which the government took action and the raw data are thereby subject to disclosure as "agency records" under the FOIA.

Accordingly, petitioners respectfully request this Court to reverse the decisions of the Courts below and deem the UGDP raw data "agency records," disclosable under the FOIA.

ARGUMENT

Introduction

This is an unprecedented case. The issue of whether the UGDP raw data, locked in a Maryland bank vault, constitute "agency records" subject to the FOIA cannot be resolved by statutory language, specific legislative history, administrative memoranda relating to intent, or the common law. Rather, this Court must be guided by the general intent of the Congress in enacting the FOIA, case law that only tangentially addresses the instant issue, an understanding of agency resistance to broad implementation of FOIA principles, and common sense.

In order to address properly the dominant issue of this action, its scope must be defined and its impact measured beyond the instant case. A judgment by this Court that the raw data are "agency records" will have

limited impact on the vast array of government sponsored research for several reasons. First, the UGDP study is unique in terms of both its original design and the role the government played in the study once its regulatory implications became apparent. Second, the UGDP is essentially a nonreplicable scientific event spanning many years, many patients, many dollars, and multi-centers.

The uniqueness and non-replicability of the study, coupled with the substantial role the government played in its design, implementation, and monitoring significantly narrow the range of government sponsored research that is affected by this case. Moreover, the government retains the right to define the parameters of "agency records" by virtue of its control of the contractual and regulatory relationship with private research grantees and the regulatory uses it chooses to make of research that it sponsors.

For these reasons, petitioners submit that public access to the raw data simply does not have the "awesome implications" postulated in the majority opinion below (A. 234). Given the broad remedial purposes of the FOIA, the implications would be greater by far if the relief sought here were denied.

The purpose of the FOIA is to permit public scrutiny of agency actions by affording broad public access to "agency records." See, e.g., Davis, *The Information Act: A Preliminary Analysis,* 34 U. Chi. L. Rev. 761 (1967). Nowhere in the Act or its legislative history is the concept of "agency records" defined. Twelve years of judicial experience have, for the most part, focused on the nine exemptions to the Act, leaving the definition of "agency records" largely unexplored. This

is surprising since the threshold question of "agency records" is basic to every FOIA inquiry.

From the relatively few cases that have dealt with "agency records," several propositions of law emerge. First, the situs of particular records in question, whether within or without agency confines, is not dispositive. See *Goland & Skidmore* v. *CIA,* No. 76-1800 (D.C. Cir. May 23, 1978) (Congressional hearing transcript in the possession of an agency held not to be an "agency record" for purposes of FOIA) and see other cases cited in Dissenting Opinion below (A. 241, fn. 3); See also *Tax Reform Research Group* v. *IRS,* 419 F. Supp. 415 (D.D.C. 1976) (records generated outside of agency and not within agency possession at time of FOIA request are "agency records" under FOIA).

Second, documents need not be prepared within the physical confines of an agency to be "agency records" *Washington Research Project, Inc.* v. *DHEW,* 504 F.2d 238 (D.C. Cir. 1974) (site visit reports prepared by outside consultants appointed to assist NIH in making grant determinations are "agency records"); *Wu* v. *National Endowment for Humanities,* 460 F.2d 1030, (5th Cir. 1972) *cert. denied* 410 U.S. 926, (memoranda and other work products prepared by outside consultant to recommend course of agency action on grant application are "agency records").

Third, traditional common law property inquiries into title and custody, whether the records are publicly or privately owned, are similarly not dispositive. See *Ciba-Geigy Corp.* v. *Mathews,* 428 F.Supp. 523 (S.D. N.Y. 1977) (UGDP raw data would be "agency records" if subject to substantial government use or control, whether or not owned by the government).

While the courts have not agreed on a specific test defining "agency records", what consensus exists generally avoids a narrow and technical approach, *cf. Nichols* v. *United States,* 460 F.2d 671, (10th Cir. 1972) *cert. denied* 409 U.S. 966; Concurring Opinion below (A. 239), in favor of a more functional approach based upon all of the circumstances of the given case.[33]

The importance of this functional approach is reinforced by a recent Report to the President by the Domestic Council Committee on the Right of Privacy. The Report documents the inappropriateness of applying traditional common law property analyses to new developments in information sharing and use.[34] What emerges is a conceptualization of "agency records", not in traditional terms of ownership or possession, but rather in terms of exploring information use relation-

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[33] Compare "significant Government involvement with the records" test, *Ciba-Geigy Corp.* v. *Mathews* at 529; test of Government involvement in "the core planning or execution of the program", Maj. Op., (A. 232 note 19); test of "significant degree of federal involvement with the records", Dissent (A. 245).

[34] "Property concepts have been central to legal theory and social and economic activity in our society. But concepts of property were formulated to deal with tangibles . . . When information, ways of dealing with information, or information products are treated as property, issues arise which differ from those resulting from the application of property theories to tangible matter. . . . Some of the characteristics of information make definition and enforcement of property rights difficult.

- Information can be infinitely shared. It can be sold, exchanged, or given away, and yet retained by the transferor.
- Information is transferred via a marker or carrier (e.g. books, magnetic tape, microfilm), but the value of the information is independent of the value of the marker."

Report to the President of the United States by the Domestic Council Committee on the Right of Privacy, NATIONAL INFORMATION POLICY, 61-62 (1976).

ships between government and outside parties on a case by case basis. Involved in the instant case is not a transfer of title but rather the need for a transfer of information. The arguments below demonstrate why the UGDP raw data must be deemed "agency records" and thereby disclosable under the FOIA.

1. Raw Data Derived From A Scientific Study Funded Entirely By A Government Agency Which Was Significantly Involved In The Study's Planning, Implementation, And Monitoring, Constitute "Agency Records" Disclosable Under The FOIA.

The UGDP was funded entirely by the National Institutes of Health (hereinafter NIH) and was subject to the regulations established by NIH and its parent agency, the Public Health Service (PHS), to govern NIH-sponsored extramural research. The fundamental principle of the extramural regulations is partnership; a partnership between NIH as the granting institution and the network of grantee institutions and scientists.[35]

PHS requires initial review and critiques of all extramural research protocols by PHS staff, outside consultants, and/or advisory groups. 42 C.F.R. § 52.13. Once approved, the research is monitored by on-site visits and review of the grantee's annual progress and financial reports. 45 C.F.R. §§ 74.82, 74.83. Major programmatic or budgetary changes require prior PHS approval. 42 C.F.R. § 52.20. The grantee's use of inventions, discoveries, or other materials resulting from

[35] Public Health Service Grants Policy Statement, DHEW Publication No. (OS) 74-50,000, July 1, 1974.

such research are subject to the approval of PHS under such terms and conditions as may be imposed. 42 C.F.R. §§ 52.22, 52.23. The government retains an unrestricted license to use the products of the scientific endeavor. 45 C.F.R. § 8.1.

PHS regulations also establish broad rights of government access to grantee records in order to promote grantee accountability. PHS officials are authorized access to:

> any books, documents, papers, and records of the grantee which [are] determined . . . pertinent to a . . . grant for the purpose of making *audit, examinations, excerpts, and transcripts.* 45 C.F.R. § 74.23 (a) (emphasis supplied).

Where records located outside the agency are determined to have long-term retention value, they can be ordered physically transferred to PHS custody. 45 C.F.R. § 74.20(b). The public at large has its own rights of access to grantee records, which can be restricted only in special and limited circumstances. 45 C.F.R. § 74.24.

Cumulatively, these regulations define the fundamental policy of partnership:

> the public interest will . . . be best served if inventive advances resulting [from research grants] are made freely available to the Government, to science, to industry, and to the general public. 45 C.F.R. § 8.0.

And again:

> It is the general policy of the Department that the results of Department research should be made widely, promptly, and freely available to other research workers and the public. 45 C.F.R. § 6.1.

Through regulatory implementation of the partnership principle, NIH has sought to achieve two important goals relevant to this case. First, it has created a mechanism assuring grantee accountability, both fiscal and programmatic. Second, it has retained virtually unrestricted rights of access to grantee records, with or without demonstration of cause.

As applied to this case, the specific regulations defining the NIH-grantee partnership are not constitutionally mandated. NIH could choose to establish a different type of partnership structure providing less (or more) grantee accountability or autonomy. Similarly, would-be grantees could decide that the benefits of NIH funding are outweighed by the costs of NIH control and therefore decline involvement in the extramural program. But where, as here, the UGDP voluntarily applied for and received NIH funding, it is and was at all times subject to the full panoply of NIH regulation and authority. *North Carolina* v. *Califano,* 445 F.Supp. 532 (E.D.N.C. 1977), *aff'd. mem.,* 435 U.S. 962 (1978). This authority included virtually unrestricted rights of government access to research records.[36]

In addition to the regulations of NIH and PHS, the UGDP was also subject to direct regulation by the FDA. The UGDP applied for and received two Investigational New Drug exemptions (INDs) from the FDA, one of which was specifically for "administrative record-keeping purposes" (A. 112). Having issued INDs, FDA had unrestricted rights of access to UGDP records for purposes of "inspection and copying" under its own regulations. 21 C.F.R. § 312.1.

[36] The majority's concerns about federalism must be viewed in light of the principle recently reconfirmed in *North Carolina* v. *Califano* that

> Without question, Congress in making grants . . . to the states should be vitally concerned with the efficient use of the funds it appropriates for that purpose . . . [and] . . . [it] . . . certainly had the power to attach to its grants conditions designed to accomplish that end. *North Carolina* v. *Califano* at 534.

While now acknowledging its comprehensive authority over HEW-sponsored research, the government has sought to characterize such authority as one rarely invoked. Great emphasis has been placed on typical grantor-grantee relationships where the government simply funds research and the private grantee conducts research with a minimum of government direction and involvement.[37] As the Director of NIAMDD has stated:

> . . . [I]t is *not the normal practice* of NIH . . . to require grantees to submit their raw data for

[37] This argument of the government was implicitly adopted by the Majority when it established its "core participation" test citing *U.S.* v. *Orleans,* 425 U.S. 807 (1976). That case raised the question of whether, by virtue of receiving federal funds, an otherwise private, non-profit corporation became a "federal agency" for purposes of the Federal Tort Claims Act. The Court found that, absent detailed federal control of the grantee's activities, the grantee could not be deemed a federal agency under the Act. The holding in *Orleans* is in accord with the nexus test established by this Court in *Jackson* v. *Metropolitan Edison,* 419 U.S. 345 (1974), defining "state action" under the 14th Amendment. However, since the instant action does not raise the question of whether a grantee is a "federal agency" by virtue of its receipt of federal funds, it should not be evaluated on the basis of whether the government assumed control of grantee activities. *Orleans* and *Jackson* are not relevant to the inquiry here, since it is not the grantee's activities that are at issue (as they are in tort or state action litigation), but rather the records generated from such activities for purposes of determining "agency records" *vel non* under the FOIA. Petitioners state, however, that even under the "core participation" test, the UGDP raw data are "agency records" in view of the special relationship developed between NIH, FDA and the UGDP.

> review and, in fact, submission of raw data to the Institute is *extremely rare*. Management of the day-to-day operations of grant-supported activities is the responsibility of the grantee. Supervision of the grantee's funded activities by this Institute is *generally limited* to review of periodic reports submitted by the grantee. (A. 147) (emphasis supplied).

Notwithstanding the accuracy of Dr. Whedon's characterization of the typical NIH-grantee relationship, the relationship between NIH and the UGDP was unique from inception through completion. Unlike most extramural research that is designed and developed privately and then submitted for federal approval and funding, UGDP design and development was itself the result of a substantial federal investment. In 1959, and again in 1960, NIAMDD awarded planning grants to six investigators to formulate a specific protocol for conducting the UGDP. This process was supported additionally by NIH's own in-house services.[38] While management of the day-to-day operations of grant activities are generally the grantee's responsibility, from the outset NIH assured itself a direct role in the conduct of the study through assignment of an employee as liaison officer to the study with *ex officio* membership on the UGDP Executive Committee.[39]

Again in contrast to its general practice, NIH evaluated UGDP renewal grant applications not only by

[38] For example, G. Donald Whedon, M.D., Director of NIAMDD, served as a statistical consultant to the UGDP. University Group Diabetes Program Address Directory (July 1969).

[39] From 1959 to 1970, three different NIH employees were assigned as liaison officers to the UGDP. As members of the Executive Committee, they were responsible for the overall management and conduct of the UGDP.

grantee progress reports but by first-hand observations and recommendations from a Policy Advisory Board. This Board was established as a result of an NIH-imposed condition for grant renewal in 1972 after the study's regulatory implications became apparent. Chaired and directed by Dr. Thomas Chalmers, an NIH employee and Director of the NIH Clinical Center, the Board met at NIH headquarters. It was assigned responsibility for overseeing all UGDP activities, including activities of the Executive Committee, rendering advice on UGDP policy matters, and reporting to NIH on UGDP developments with recommended courses of action.

Finally, and significantly, while NIH's "normal practice" did not entail submission of grantee raw data for review, the UGDP raw data were twice submitted for review for persons acting under NIH sponsorship or direction; first Biometrics, from 1972 to 1974, and then the FDA, from 1975 to 1978. If submission of raw data for outside review was, by Dr. Whedon's own characterization, "not the normal practice" and "extremely rare", then the UGDP was not the normal NIH sponsored study. NIH was significantly and directly involved in the "core" of the UGDP, and UGDP records are therefore "agency records" under the FOIA.

The Majority opinion below expresses the policy concern that, should the raw data be considered "agency records", principles of freedom of science and grantee autonomy would be compromised. Petitioners themselves are physicians and scientists who have received federal grants to support their work and are keenly sensitive to any action, governmental or otherwise, that would compromise such principles.

However, disclosure of the raw data in this case would in no way impact upon grantee autonomy and, instead of infringing upon freedom of science, would serve to advance and fulfill it.[40]

To understand why this is so, one must appreciate that the UGDP raw data, locked in a Maryland bank vault, are a unique scientific resource. UGDP investigators were provided with more than fifteen million federal dollars to conduct this unprecedented twelve-site study. The patient observation phase alone lasted in many cases for over fifteen years. In addition to the logistical problems of attempting replication, the years required to collect comparable data would render such data of no value to contemporary medical and scientific debate concerning the proper treatment of diabetes mellitus.[41]

Replication is one of the processes by which science is made accountable. It assures the accuracy of re-

[40] The principle of grantee autonomy is not at issue in this action. That principle is concerned solely with preventing the Government from controlling legitimate scientific inquiry by requiring science to be conducted by a particular means, or towards a particular end, or with some restriction imposed upon a grantee's right to communicate scientific findings freely and openly to the public. See, e.g., Robertson, "The Scientist's Right to Research: A Constitutional Analysis," 51 CALIF. L.R. 1203 (1978). Grantee autonomy is not infringed or even involved when the issue is the extent to which a federal grantee's product is to be shared under the FOIA with scientific colleagues and other members of the public. See also Mason, "Current Trends in Federal Grant Law—Fiscal Year 1976," 35 FED. BAR 163 (1976).

[41] There are serious questions at this point whether the UGDP could ethically be replicated because of the manner in which the study was conducted; i.e., administering to diabetic and non-diabetic patients fixed doses of insulin, which was contrary to either then-accepted or now-accepted clinical practice of variable dosage administration.

ported findings, the validity of underlying data, and the core integrity of the scientific endeavor.

> Scrutiny in science normally means replication. . . . One would expect mathematics to be relatively free from fraud . . . because it is relatively easy for an expert to check the evidence—it is mainly in the published article. For empirical science, the evidence remains behind . . . closed doors . . . and *only summary numbers are presented in publications. If one suspects the evidence supporting a study, the usual procedure is to replicate the work.* Weinstein, "Fraud in Science," 59(4) *Social Science Quarterly,* 639, 645 (1979). (emphasis supplied).

Government sponsored multi-center studies like the UGDP have inherent problems both clinical and ethical:

> It has proven very difficult to ensure that all investigators working on a common problem will actually carry out their observations according to common, agreed upon standards. The difficulties become particularly marked when the study involves repeated clinical observations which by their very nature allow the intrusion of a large subjective element.
>
> Finally, there is almost bound to be a higher degree of potential conflict of interest in the collaborative programs than in other parts of NIH operations. . . . The people one turns to for advice on whether or not to enter a certain project area are likely to be the same people who design a possible project, provide opinions on its feasibility or merit, and finally receive the funds to carry it out. Report to the President, "Biomedical Science and its Administration: A Study of NIH" (1965) at 204-205.

Similar charges have been leveled directly at the UGDP.[42]

Where, as here, a study is not replicable, validation of its findings and determination of its integrity can only be provided by corroboration of existing data. Thus corroboration, like replication, is an essential verification methodology.

For the above reasons, petitioners contend that a voluntary partnership existed between the government and the UGDP based upon comprehensive regulations authorizing unrestricted government access to the UGDP raw data. The above discussion further demonstrates that the government was a core participant in the design, implementation, and monitoring of the UGDP. Disclosure of the UGDP raw data will in no way infringe upon grantee autonomy or the freedom of scientific inquiry. Accordingly, the UGDP raw data are "agency records" under the FOIA.[43]

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[42] In addition to Dr. Bowen's questioning of respondent Klimt's integrity and the possibility of manipulation of the raw data at the Coordinating Center, (Statement of Angela Bowen, M.D., see note 10 *supra*) respondent Klimt was accused of conflict of interest by Dr. Shirley Weisenfield, another UGDP investigator, and was asked to resign from the study in 1971. This charge arose out of Klimt's serving as full-time Director of the Office of Scientific Coordination at the FDA while at the same time continuing as Director of Coordinating Center operations. Letter from Dr. Klimt to Dr. Shirley Weisenfield (December 16, 1970). (App. Br. 16a).

[43] For purposes of defining the scope of "agency records," the Government has suggested a difference between research conceived without a "specific regulatory objective in mind" and other types of research with regulatory implications from the outset. (A. 146) See also Maj. Op. below (A. 228). Petitioners submit that the UGDP actually represented a third type of research which, though non-regulatory at outset, became increasingly regulatory as the study progressed, with concomitantly closer Governmental monitoring and involvement. It should be pointed out, moreover, that in promulgating its FOIA regulations, the FDA specifically considered and rejected any distinctions between regulatory and nonregulatory research for FOIA purposes.

> Upon reconsideration, the [FDA] concludes that it is often not feasible to distinguish between regulatory and nonregulatory testing and research, and that, in any event, there is no sound public policy reason for not disclosing both types of testing and research. 39 Fed. Reg. 44625 (1974).

Thus under the FDA's FOIA regulations, the raw data of FDA-funded research are "agency records" even if the research is conducted by private grantees. 21 C.F.R. § 20.105(d).

2. Raw Data Resulting From Government-Funded Research Which By Contract And Regulation Are Fully Accessible To The Government And Which Have In Fact Been Partially Audited By And At The Direction Of The Government Are "Agency Records" Disclosable Under The FOIA.

In prior proceedings below, HEW argued, first, that it had "no authority" to order production of the UGDP raw data, and second, that even if so authorized, it had no obligation to "fetch" the data for FOIA purposes.

For HEW to deny its authority over the raw data is to ignore the plain meaning of its own regulations. These regulations, as discussed above (pp. 28 to 31), grant unrestricted rights of access and control over the data to both NIH and FDA. Therefore, this argument fails.

The "fetch-it" argument is equally defective, since whatever its merits in the abstract, the UGDP raw data have been "fetched" on at least two occasions as a result of HEW directives. Petitioners submit that this fact, by itself, is dispositive in determining the govern-

ment's authority over and involvement with the data, and that the UGDP raw data are therefore "agency records" under the FOIA.

The first outside review of the data resulted directly from an NIH contract which "urged" Biometrics to "utilize all resources necessary" to assess the UGDP statistics "in-depth" and report back to NIH.[44] On the basis of its review, including its direct access to the raw data, Biometrics prepared a Report which concluded with "moderately strong" support of the UGDP study.[45]

HEW sought to make much of the fact that, while the raw data were reviewed by an HEW contractor for purposes of rendering advice to the agency, the data still had not been directly reviewed by HEW itself. According to this argument, HEW's rights of access and control over the data remained "inchoate" and therefore the UGDP raw data were not "agency records". Brief of Federal Appellees, U.S. Circuit Court of Appeals, at 34.

Petitioners contend that this argument lacks merit, since there is no intent gleaned in either the FOIA or its underlying principles of broad disclosure to allow common law agency distinctions to dictate the scope of "agency records". For the government to suggest that data utilized by a government contractor in preparation of a final report to the government are not disclosable under the FOIA is erroneous.[46]

[44] Biometric Report, at 585.

[45] Biometric Report, at 599.

[46] See, e.g., 21 C.F.R. § 20.105(d) which requires FOIA access to all raw data and other working materials of an FDA research contractor at the time the final contract report is disclosed. Additionally, it should be noted that Biometrics functioned as a group "established or utilized by one or more agencies in the interest of obtaining advice" (5 U.S.C. App. I § 3(2)) and was therefore an advisory committee under the Federal Advisory Committee Act. All "documents which were made available to or prepared for" the Biometric Committee are available to the public (5 U.S.C. App. I § 10(b)). Under this rationale, all of the UGDP data which were retrieved from the Coordinating Center by Biometrics, if not the entire data base made available to them, were public records fully subject to FOIA as early as February, 1975. (See also FDA regulations governing use of advisory committees, 21 C.F.R. § 14.75(8)).

Even assuming, *arguendo,* that the definition of "agency records" turns on the government's direct review of the raw data, the fact here is that the government directly reviewed the data by conducting an FDA audit. The audit team, composed of physicians, statisticians, and investigators from FDA staff, acted under designation by NIH

> to conduct [an] audit and *exercise all authority* granted to NIAMDD under 45 CFR Part 74 (App. Br. 18a) (emphasis supplied).

This authority was exercised at several different locations, including the Coordinating Center, at least one of the clinical centers, and at FDA offices. A variety of different methods were chosen for conducting the audit, including direct copying, transcribing, and abstracting of forms, oral and written communications, and telephone and computer link-ups. The net result is that the government exercised its authority to audit all of the raw data.

Petitioners submit that, having been subjected to the full auditing authority of the government, the UGDP raw data are "agency records" for purposes of the FOIA. The specifics of where the government decided to perform this audit, whether at the FDA or at the Coordinating Center or at some alternative site, are not

relevant for purposes of the FOIA since the government had the authority to inspect the data at whatever location it wished. Similarly irrelevant are the mechanics of how it chose to perform the audit since, again, it had the right to perform the audit in whatever manner it chose.

The FDA's decision to perform the audit in a partial and selective manner is not relevant to the issue of whether the data are "agency records" under the FOIA. The entire fabric of the Act is to encourage broad disclosure by government agencies in order to minimize the possibility of "secret law." [47] When only a portion of an otherwise FOIA-exempt memorandum was disclosed by the Maritime Subsidy Board in the context of regulatory action, the Court ordered production of the entire memorandum for public inspection under the FOIA. *American Mail Line, Ltd. et al.* v. *Gulick,* 411 F.2d 66, 73 (D.C. Cir. 1969). Similarly, the FDA's FOIA regulations provide that a record otherwise exempt from disclosure is *fully* available to the public under the FOIA to the extent that portions thereof are publicly disclosed. 21 C.F.R. § 20.81(a). The FOIA's basic purpose is

> to protect the people's right to obtain information about their government, to know what their government is doing and to obtain information about government activities and policies and to *remedy the mischief of arbitrary and self-serving withholding* . . . Note, A Review Of The Fourth Exemption of the Freedom of Information Act, 9 Akron L. Rev. 673, 694 (1976), quoted in *Westinghouse Electric Corp.* v. *Schlesinger,* 542 F.2d 1190, 1210 (4th Cir. 1976) (emphasis supplied).

[47] In enacting FOIA, "Congress . . . was concerned with the dilemma in which the public finds itself when forced to litigate with agencies on the basis of secret laws or incomplete information." *Weisberg* v. *U.S. Dep't of Justice,* 489 F.2d 1195, 1199 (D.C. Cir. 1973).

Here, where an HEW agency has performed an audit of an HEW sponsored and endorsed study, relied upon for HEW regulatory activity, the FOIA plays an essential role in minimizing the potential agency mischief of "arbitrary and self-serving withholding."

To allow an agency to define the metes and bounds of "agency records" by choosing whether, where, and how to exercise control over records is to invite FOIA gamesmanship. The early interaction between the FDA and the Coordinating Center demonstrates their awareness of the FOIA implications of the audit.[48] There is considerable evidence to suggest that decisions about the scope, nature, and location of the audit were directly influenced by the desire to limit the agency's FOIA file (see 53, *infra*). Indeed, HEW's conscious use of "data havens" to shelter documents from the FOIA is specifically discussed in the Report of the Domestic Council Committee on the Right of Privacy, a committee of which HEW is a member.[49]

[48] Shortly after issuance of the District Court opinion below, respondent Klimt contacted the FDA to determine whether it was still necessary for the audit to proceed: "[I] know the time commitments of [FDA] staff are strained, and possibly the most favorable verdict of the District Court of Columbia may change the situation somewhat." Letter from Christian R. Klimt to J. Richard Crout, March 1, 1976.

[49] "Another issue that has emerged from implementation efforts concerns the scope of the Freedom of Information Act. Because the Congress and its offices (such as the General Accounting Office and the Library of Congress), the States, and the private sector including Federal contractors, are not covered by the Act, agencies sometimes attempt to take information that would normally belong in their own files and maintain the material in these 'data havens.'

In enacting the FOIA, Congress intended "to pierce the veil of administrative secrecy" and to ensure that documents were not shielded from public disclosure by "unwilling official hands." *Department of the Air Force v. Rose*, 425 U.S. 352, 361 (1976).

> Before 1976, the Administrative Procedure Act contained a Public Information section full of loopholes which allow[ed] agencies to deny legitimate information to the public: When Congress acted to close these loopholes, it clearly intended to avoid creating new ones. *Bristol Myers Company* v. *F.T.C.*, 424 F.2d, 935, 938 cert. denied 400 U.S. 824 (D.C. Cir. 1970).

Petitioners assert a right to review *all* the UGDP raw data and not just the data selected by the government for release to the public.[50]

For instance, Department of Health, Education and Welfare personnel reported to us that they no longer accept possession of drafts of General Accounting Office audit programs because it cannot shelter the documents from FOIA requests. Instead, HEW personnel inspect the drafts at GAO which is exempt from the FOIA.

"The extent of the 'data haven' problem is not yet clear, but insofar as the Federal Government must meet a disclosure standard that exceeds the policies in other sectors, pressures exist for Federal Agencies to 'hide' information in exempt systems." Report to the President of the United States by the Domestic Council Committee on the Right of Privacy, NATIONAL INFORMATION POLICY 51-52 (1976). (emphasis supplied)

[50] The principle that an entire record must be available for disclosure whenever any portion thereof is sought to be relied on is familiar in other areas of the law as well. For example, the common law principle of "completeness", as embodied in the Federal Rules of Evidence (Rule 106), states:

> When a writing or recorded statement or part thereof is introduced by a party, an adverse party may require him at that time to introduce any other part or any other writing or recorded statement which ought in fairness to be considered contemporaneously with it.

Principles of discovery are analogous:

> If only a part of a deposition is offered in evidence by a party, an adverse party may require him to introduce any other part which ought in fairness to be considered with the part introduced and any party may introduce any other parts. F.R.C.P. Rule 32.

3. RAW DATA RESULTING FROM GOVERNMENT FUNDED RESEARCH WHICH HAVE BEEN ABSORBED INTO THE FEDERAL DECISION MAKING PROCESS AND FORM THE BASIS FOR AGENCY REGULATORY ACTION ARE "AGENCY RECORDS" DISCLOSABLE UNDER THE FOIA.

The question addressed by the District of Columbia Court of Appeals of whether the UGDP raw data are "agency records" was determined by the majority solely on the basis of "the study and granting activities . . . of NIAMDD." (A. 228). The majority went even further to suggest that FDA's regulatory actions in response to the UGDP were irrelevant for purposes of the FOIA (A. 228). This was apparently based on the view that to the extent the UGDP formed the basis for agency action and the raw data were not forthcoming, alternative relief could be sought under the Administrative Procedure Act (APA). 5 U.S.C. § 551 *et seq.*

Petitioners disagree and contend that FDA's reliance on the UGDP raw data for regulatory decision making is itself grounds for finding that the data constitute "agency records." Further, when combined with the other indicia of government involvement with the data, (See 28 to 36 *supra.*), this absorption of the raw data into the regulatory process inextricably renders them "agency records."

Petitioners will demonstrate: a) that the UGDP study in fact formed the basis of extensive FDA regulatory action; b) that FDA reliance on the UGDP study included direct reliance on the UGDP raw data; c) that remedies under the APA are no substitute for the remedies of the FOIA; and d) that to disregard the factors of agency reliance and regulatory action as indicia of "agency records" is to create the serious potential for FOIA evasion and abuse.

a. *FDA Reliance On The UGDP Formed The Basis For Regulatory Action*

Even prior to publication of the UGDP findings in December 1970, the FDA had adopted and promulgated a formal agency position in reliance on the UGDP. In a statement delivered to the Subcommittee on Intergovernmental Relations on June 9, 1970, then Commissioner Charles C. Edwards, M.D. described the early relationship between the FDA and the UGDP as follows:

> In 1968 we received an initial verbal communication from the UGDP pointing out that early reports seemed to show an excess mortality in those groups assigned to tolbutamide compared to other groups. At that time the preliminary data had not been completely analyzed . . .
>
> In June 1969 a progress report on tolbutamide was received by the FDA. At a meeting with representatives of UGDP they presented their data and a statistical evaluation. *The FDA presented this material to our Medical Advisory Board who recommended that the FDA review the raw data and continue in close contact with the UGDP.*
>
> However, further data were not forthcoming until March 1970 when we received an advance copy

> of the manuscript of the report on this study. This report was reviewed by the FDA and an *ad hoc* expert advisory committee. Despite a number of limitations in the study, the agency and the advisory committee agreed with its stated conclusions . . . As soon as the *ad hoc* expert advisory committee had reached its conclusions, the Food and Drug Administration immediately issued a press release on the subject in which it was emphasized that the oral antidiabetic drugs should be used only for those patients who are not controlled by diet alone, that the dosage should be adjusted to the individual needs of the patient, and that patients taking these drugs should continue on their prescribed regimen until otherwise advised by their physician. The findings of the study and our conclusions were also relayed immediately to the practicing physicians through a telegram sent to all county medical societies with a request that the information be disseminated as rapidly as possible. In addition, we are in the process of mailing directly to every physician in the country a message setting forth the results of this study and our recommendations based on it. The labeling of the products will be changed to require the drug firms involved to institute long-term studies on the use of their products in various types of diabetic patients.[51]

Commissioner Edward's statement of nine years ago, before the UGDP controversy erupted full-blown, is significant in several respects. First, it indicates that once the UGDP's preliminary conclusions were made available to the FDA, the FDA actively became involved with the UGDP. The study's conclusions were

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[51] Oversight Hearings Before the Subcommittee on Intergovernmental Regulations of the House Committee on Government Operations, 91st Congress, 2nd Session (Statement of Charles C. Edwards, M.D., Commissioner of Food and Drugs, at 15-17).

perceived to have immediate regulatory implications for the FDA. Second, the statement reflects FDA's early awareness of the significance of the raw data and the importance of taking no position until after the data had been reviewed by the agency. Third, the statement confirms the agency's adoption of the UGDP conclusions without having undertaken any review of the underlying raw data.

What followed was a series of FDA regulatory actions based primarily, if not exclusively, on the UGDP:

- *October 30, 1970*—FDA issues a Report on Oral Hypoglycemic Agents, stating that "despite a number of limitations in the study, *the Food and Drug Administration agree(s) with the University Group Diabetes Programs' stated conclusions . . .*" Oral Hypoglycemic Agents: Report of the FDA (October 30, 1970). (Emphasis supplied).
- *May, 1972*—FDA issues a new special warning for diabetes drug labeling which, if implemented, would necessitate many diabetic patients being removed from the oral hypoglycemic medications. "The long term study provided the basis for the labeling." "Final Labeling Approved for Oral Hypoglycemic Drugs," FDA Drug Bulletin (May 1972).
- *July 7, 1975*—FDA again proposes a labeling warning stating:

> The judgment of the Commissioner that changes must be made in the labeling of the oral hypoglycemic drugs to reflect the findings of the UGDP study is well known . . .
>
> The warning proposed in this labeling is based primarily on a thorough review and evaluation of the UGDP study . . .

> The Commissioner reaffirms his view that the UGDP study is an adequate and well-controlled clinical trial.
>
> . . . The Commissioner believes that the UGDP study is a validly conducted trial . . . 40 Fed. Reg. 28591 (1975).

- *July 25, 1977*—Secretary of HEW suspends phenformin as an imminent hazard, citing the UGDP as the only prospective study of phenformin available and one of four basic sources relied upon. In re: New Drug Applications for Phenformin, Order of the Secretary Suspending Approval at 38 (July 25, 1977).
- *October, 1977*—FDA witnesses describe the UGDP as "the best evidence" available in support of FDA's position during phenformin administrative hearing. In the Matter of the Proposal to Withdraw Approval of the New Drug Applications for Phenformin Hydrochloride (FDA Docket No. 77N-0150) Hearing Exhibits B-481 at 8, B-485 at 16, and Hearing Transcript at 341.
- *November 14, 1978*—FDA labeling proposal, the same proposal issued by FDA in 1975, is reissued by the agency based on the agency's full endorsement of the UGDP. 43 Fed. Reg. 52732 (1978).

As Judge Bazelon stated below, "A clearer affirmation and reliance on the UGDP study is hard to imagine" (A. 252).

b. *FDA Relied Directly On The UGDP Raw Data*

The supposed distinction suggested by the government between the published UGDP results and the underlying data is scientifically without merit. In the

context of scientific research, as recognized by HEW's own regulations, "results" necessarily include not only a study's end-product but its supporting raw data and methodology. 42 C.F.R. § 52.22. By requesting Biometrics to conduct a thorough review of the UGDP, a review that necessarily encompassed the raw data, NIH itself recognized the meaningless nature of this distinction. Lingering reliance upon such a distinction ended when the FDA itself audited the raw data.

Recent regulatory actions taken by the FDA and HEW have been based specifically on the raw data and not just on published conclusions. When the FDA resumed proposed relabeling of oral hypoglycemic drugs four months after release of the final Biometrics Report, 40 Fed. Reg. 28587 (1975), the FDA explicitly recognized the "intense criticism" to which the UGDP conclusions had been subjected and the "wide-spread belief . . . among many physicians that the UGDP study was somehow flawed in terms of its design and execution," *Id.*, at 28588. Accordingly, it "decided to postpone implementation of the warning until [the Biometrics Report] was published." *Id.*, at 28589. After Biometrics conducted "extensive new analyses of the UGDP data taking into account the effect of various baseline variables and cardiovascular risk factors" *Id.*, at 28590, the FDA "accepted" Biometrics' opinion that the findings of increased cardiovascular mortality could not "reasonably be attributed to scientific shortcomings in the study." *Id.*, at 28591.

> Under these circumstances, a clear warning is necessary even though a residual uncertainty over the correctness of the study may be present. *Id.*, at 28591.

Similarly, when HEW ordered suspension of the marketing of phenformin in July 1977 based in part on the UGDP, the Order cited the FDA's own analysis of the study:

> The FDA, which is experienced in interpreting and analyzing incidence figures for adverse reactions, has examined [the UGDP] statistics and concluded that the incidence figures are scientifically valid. In Re: New Drug Applications for Phenformin, Order of the Secretary Suspending Approval at 11 (July 25, 1977).

Finally, in November 1978, the FDA reissued in proposal form, the relabeling regulations proposed in July 1975. This latest action was based explicitly upon the FDA's audit of the raw data.

> [W]hile there are certain errors and discrepancies between the data file on the UGDP study and the published reports, none of these appears of sufficient frequency or magnitude to invalidate the finding that cardiovascular mortality was higher in the [oral hypoglycemic] groups. . . . FDA Audit of the University Group Diabetes Project at 2 (October 16, 1978).

Therefore, by government admission, the UGDP raw data, as well as the published conclusions, have been relied upon directly by HEW and have thereby been "absorbed into the federal decision-making process." Dissenting Opinion below (A. 255). As such, they are "agency records" under the FOIA. See *SDC Development Corporation* v. *Mathews,* 542 F.2d 1116 (9th Cir. 1976) (test of "agency records" is whether they reflect the agency's decision-making functions); *Tax Reform Research Group* v. *IRS,* 419 F. Supp. 415 (D.D.C. 1976) (documents relied on by agency for pur-

poses of regulatory action but no longer in agency possession are "agency records" in order to allow the public to know the full basis for agency decisions).

c. *Remedies Under The APA Are No Substitute For Remedies Under The FOIA.*

Petitioners claim that the raw data are "agency records" under the FOIA because they have been absorbed into, and relied upon by, the federal decision making process. Petitioners do not claim any special entitlement to the raw data by virtue of their status as an interested party in related regulatory proceedings. Petitioners recognize that their right to obtain information under the FOIA is "to be measured by the right of the public to obtain the same information". *Nix* v. *United States,* 572 F.2d 998 (4th Cir. 1978).

But if petitioners' rights to the raw data under the FOIA are not enhanced by their needs as litigants, neither should they in any way be diminished for this reason. While the Majority below has recognized this point in theory, its denial of FOIA relief relies, to a considerable extent, on the availability of alternative remedies to petitioners. Judge MacKinnon's Concurring Opinion suggests that no harm to the public would result from the denial of FOIA access to the UGDP raw data because "they may be subpoenaed by interested parties" (A. 239). Judge Leventhal's opinion for the Majority refers petitioners to remedies available under the APA as a means of challenging agency action taken without disclosure of the data. However, these alternative remedies have proven to have multiple and serious limitations, both procedural and substantive.

Procedurally, petitioners' standing as a party in UGDP regulatory proceedings has been strenuously contested by the FDA, most notably at the hearings at the FDA in 1977 to review HEW's suspension of phenformin. In that case, the Administrative Law Judge sustained the FDA's objection to petitioners' standing on the basis of an FDA regulation explicitly conferring full-party status only on drug manufacturers. 21 C.F.R. § 314.200(a). As a result, petitioners' role in the hearings was limited to the submission of written statements and briefs, and petitioners had no opportunity to testify or to examine and cross-examine witnesses.

Unlike FOIA proceedings where the burden is on the government to prevent disclosure of information, APA proceedings shift the burden to the private litigant to prove that failure of the government to disclose information is erroneous in fact or in law. 5 U.S.C. § 706(2); See, e.g., *F.C.C.* v. *National Citizens Committee for Broadcasting, et al.,* 436 U.S. 775, 802-03 (1978). In the phenformin proceedings, petitioners were placed in the untenable position of having to demonstrate error in the FDA's failure to include in the administrative record *all* of the UGDP raw data without being able to demonstrate what the inclusion of such data might have proven.[52]

Alternative administrative and judicial remedies have proven for petitioners to be the pursuit of pyrrhic process. Nine years after the government first relied on the UGDP as the basis for regulatory action, and after numerous administrative and judicial pro-

[52] See footnote 25 and pages 17 to 19 *supra.*

ceedings in which the UGDP has been challenged,[53] the UGDP raw data remain largely secreted from public view. Only by permitting public access to the entire UGDP raw data can the validity of the study be determined. The social risk of misapplying the UGDP has been and remains a generation or more of diabetic patients receiving improper treatment.

[53] *Oral Hypoglycemic Labeling.* Petitioners' litigation in the First Circuit Court of Appeals, described at p. 10 *supra*, resulted in a remand to the FDA with a judicial prayer for discussion and resolution of the UGDP controversy. FDA proceeded to revoke the regulation requiring fair balance in UGDP labeling relied upon by petitioners. 40 Fed. Reg. 28582 (1975). Petitioners, therefore, returned to Court in *Bradley et. al.* v. *Califano et. al.*, No. 76-401-M (D. Mass.) on the relabeling issue. Despite the continuing harm which has resulted from the FDA position on the labeling, the court challenge must await final FDA action on the labeling proposal before a complete administrative record is available.

Phenformin. Petitioners challenged the HEW suspension of phenformin in the United States District Court for the District of Columbia (*Forsham et al.* v. *Califano*, No. 77-1478). The District Court denied petitioners' motion for a preliminary injunction on October 21, 1977, which denial was appealed to the Court of Appeals (No. 77-2071). However, on April 10, 1979, the Court of Appeals dismissed the appeal, stating that issues involving the suspension were mooted since the drug had been permanently withdrawn from the market on November 15, 1978 after the administrative hearing process.

Petitioners had also filed, on December 18, 1978, a Petition for Review to the U.S. Court of Appeals for the District of Columbia Circuit (No. 78-2288) contesting the validity of the withdrawal hearing. (*Forsham et al.* v. *Califano et al.*). A primary issue was again the application of the UGDP study by FDA to support its position at the hearing despite the agency's failure to submit the raw data of the study as required by FDA's prehearing regulations and due process principles generally. Petitioners also challenged the FDA's denial of petitioners' rights actively to participate in the hearing process. This action appealing the hearing was dismissed simultaneously with the appeal on the imminent hazard suspension. The Court of Appeals ruled that petitioners lacked standing to challenge a drug withdrawal under 21 U.S.C. § 355(h).

d. *Restrictive Definitions of "Agency Records" Invite FOIA Abuse.*

To accept the government's restrictive definitions of what constitute "agency records" is to create the potential for agency evasion of the spirit and letter of the FOIA. That such evasion occurs is demonstrated in the instant case.

The FDA audit was announced while petitioners were pursuing FOIA remedies in the District Court below. Thus, both the FDA and the Coordinating Center were aware from inception of the audit of the FOIA implications of their actions.

Petitioners contend that the scope, locations, and nature of the audit were tailored by the government with FOIA considerations in mind:

> . . . Dr. Klimt stated that prior to initiation of any such audit, he would require from us a written statement including what materials we wished to review . . . He requested that we not include in our letter any reference to copying of materials, stating that he had a previous agreement with Dr. Crout that no patient data would be copied and removed from Baltimore to Rockville. He further noted that *if this were done the data involved would be in the possession of the government and would be available under Freedom of Information to Neil Chayet and the Committee for the Care of the Diabetic, an action which had thus far been successfully opposed in court because the data involved were not in the possession of the government.*
>
> Memorandum of Telephone Conversation between Dr. Klimt and Dr. Lisook, FDA Auditor, March 10, 1976, Subject: UGDP Audit by FDA (emphasis supplied).

When respondent Klimt received no assurance from Dr. Lisook as to the scope of the audit, he telephoned Dr. Crout at his home to pursue the matter further:

> Dr. Klimt called me at home regarding the upcoming UGDP audit. He wanted to express his concern that Dr. Lisook was intending, as Dr. Klimt understood it, to copy a large number of documents at the UGDP Coordinating Center. Dr. Klimt stated to me that he felt this was not part of his understanding with me during our previous meetings. I indicated to him that, to my memory, this was the first conversation in which we had specifically discussed the point in any depth. I had stated to him previously that we had no intent of copying documents unnecessary to a careful audit —i.e., *we would not use our investigating authority as a mechanism for removing and ultimately making public all the data in his files*—but we did feel that a careful investigation would require the copying of certain material to document our own findings. FDA Memorandum of Telephone Conversation between Dr. Klimt and Dr. Crout, March 18, 1976. Subject: UGDP Audit by FDA (emphasis supplied).

By August, 1976, the government's initial plan for a large-scale audit and extensive copying of the raw data had changed. This change was reflected in correspondence from Dr. Crout to respondent Klimt:

> "[W]e no longer visualize copying any volume of documents, but have instead constructed a three page form to be completed in a stepwise manner in Rockville, Baltimore, and if necessary in Boston." Letter from Dr. Crout to respondent Klimt (August 3, 1976).

The practical result of this revised auditing approach became apparent shortly thereafter when it came time for the government to fulfill its pledge at oral argument to deliver to petitioners all audit data gathered. FDA was the first to acknowledge the serious limitations of the information it provided.

> If these documents are not as informative as you might like, it is because most of our audit was performed by abstracting data from UGDP records rather than by making copies of voluminous available records. (App. Br. 19a-20a).

The documents, not surprisingly, were scant, owing to the FDA's self-imposed limitations on the audit. Having had the opportunity to review all of the UGDP raw data for purposes of a thorough audit, the FDA chose to audit only selected portions, to abstract even fewer portions, and to copy and disclose under FOIA only that minute fraction of the UGDP raw data which it had effectively pre-designated for disclosure under the FOIA.[54]

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[54] Further evidence of the manner in which FOIA principles were circumvented or ignored by the FDA came when petitioners attempted to obtain a copy of the audit report prior to its public release. Petitioners' request was denied August 7, 1978 on the grounds that the report was still "investigative in nature" and an "intra-agency memorandum." However, when the final report was publicly released on November 14, 1978, it became apparent from enclosures thereto that FDA had shared earlier drafts of the report with the UGDP Coordinating Center that was the target of the investigation and had even received return comments. Under the FDA's FOIA regulations, neither of the cited exemptions could lawfully be invoked. 21 C.F.R. § 20.64(c) states that an investigatory record disclosed to the subject of an FDA investigation loses its FOIA investigative status and is immediately subject to public disclosure (with exceptions not here relevant). Further, under well settled FOIA principles and FDA regulations (21 C.F.R. § 20.62), any reasonably segregable factual portion of an intra-agency memorandum must be made available

Petitioners contend that selective screening of records by government agencies is violative of the spirit of the FOIA. The FOIA does not contemplate allowing government agencies, by their action or inaction, to restrict intentionally the level of public disclosure of "agency records." To do so would subvert the very essence of the Act—freedom of information to the public.

for public disclosure. If the UGDP Coordinating Center received an advance copy of the factual portion of the draft audit report, then that same portion should have been immediately available at petitioners' request. If the Coordinating Center received more than the factually segregable portion, then for the FDA to have continued to shield the report from disclosure as an intra-agency memorandum is to suggest that the FDA viewed the Coordinating Center as an integral part of internal agency operations.

CONCLUSION

For the foregoing reasons, petitioners respectfully request this Court to reverse the decision of the Court of Appeals for the District of Columbia Circuit and designate the UGDP raw data to be "agency records" under 5 U.S.C. § 552 and therefore subject to disclosure to petitioners and other members of the public.

Respectfully submitted,

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APPENDIX TO BRIEF

(Cited in brief as App. Br.)

Controversy Over Study of Diabetes Drugs Continues for Nearly a Decade. 203 Science 986 (1979)

A bitter altercation raises major issues facing clinical scientists and regulatory agencies

In the next few weeks, the Food and Drug Administration will decide whether all oral anti-diabetes pills should carry warning labels saying they are toxic. And in the near future, the U.S. Supreme Court will decide whether to hear arguments that data from federally funded research should be publicly available. These are issues arising directly from a highly controversial clinical trial—a trial whose results may portend the kinds of difficulties facing supporters of the large crop of clinical trials now being conducted.

The past decade has been a time of bitter debate and accusations within the diabetes community, a time when eminent scientists and physicians became sharply polarized in their opinions on a subject that is, at best, murky. The altercation has been so vituperative that an authority in the field calls it "the most shameful in the history of modern medicine."

The dispute is over the use of oral anti-diabetes drugs. These pills, which lower blood sugar, are popular with doctors and patients and are extremely profitable for the drug companies. But administrators of a major clinical trial, called the University Group Diabetes Project (UGDP), concluded 10 years ago that the drugs are not efficacious and that they are probably toxic as well. This conclusion has since been sharply attacked by one group of physicians and scientists and evangelically promoted by another and the trial itself is the focus of a heated debate.

The tale of the UGDP is more than just the story of an internecine fight. It raises major issues facing clinical scientists and regulatory agencies today. These include the way people behave when their beliefs are challenged by data that are themselves open to challenge, the role of the Food

and Drug Administration (FDA) in taking a stand on controversial issues, the proper treatment of adult-onset diabetics, the public's right to access to data from government-funded studies, and the ultimate value of clinical trials.

The principal figures in the UGDP story are:

- The FDA, which has, by its actions, fanned the fires of the debate. In 1968, the FDA immediately endorsed the UGDP's conclusion that one of the oral anti-diabetes drugs might be toxic and decided to put warning labels on all such drugs. Although court challenges have thus far prevented the agency from going ahead with its requirement for warning labels, it has as yet refused to budge an inch in its position that the labels are necessary.

- The Committee for the Care of the Diabetic (CCD), a group of diabetologists who banded together to contest the FDA's endorsement of the UGDP. The CCD is an impassioned and sometimes strident group which is totally convinced that the UGDP must be discredited.

- Christian Klimt, a biostatistician at the University of Maryland Medical School in Baltimore, who was in charge of the computer coding and analysis of the UGDP results. He has thus far refused to make the study's raw data available and has been accused of manipulating them.

- Angela Bowen, a diabetologist now in private practice in Olympia, Washington, and formerly a principal coinvestigator in the UGDP. Bowen resigned from the study in part because of Klimt's failure to release patient records. She has played a key role in making and publicizing allegations about Klimt.

The UGDP began in 1961 as a major trial to answer questions of vital importance to the country's 2.5 million adult-onset diabetics: What is the value of lowering blood sugar concentrations? and, Are oral anti-diabetes agents a safe and effective way of doing it? These agents, which were introduced in the 1950's, were immediately welcomed by some physicians because they enabled patients to lower their blood sugar level without insulin injections and to avoid the unpopular and often unsuccessful diets prescribed for overweight diabetics. Other physicians questioned the usefulness of the drugs, arguing that it was not at all clear that lowering blood sugar prevents the complications of diabetes and that perhaps overweight patients whose only symptom is elevated blood sugar should just be urged to diet. (Most adult-onset diabetics are overweight and weight loss alone often controls their diabetes.)

The UGDP was to be the world's biggest and best-designed clinical trial. As one of the first large-scale trials ever conducted, it served as a model for the large crop of clinical studies that followed it. When the UGDP began, the general feeling in the scientific community was enthusiasm for its methods and goals. Only later was this enthusiasm to sour and the study to come under attack.

The trial was conducted at 12 university diabetes clinics which recruited a total of 1027 volunteers. The study's design stipulated that the volunteers be adult-onset diabetics with expected lifespans of at least 5 years. The data from the clinics were sent to a coordinating center run by Klimt for analysis.

At the start of the trial, the patients were randomly divided into four groups: those who received a placebo, those who received a fixed dose of insulin, those who received a variable dose of insulin depending on their blood sugar level, and those who received a fixed dose of tolbutamide, an oral anti-diabetic drug. All patients were also given a low-calorie diet. Two years later, phenformin, another oral anti-diabetes drug that had just come on the market, was added to the study.

From 1961 to 1968, UGDP data were gathered and analyzed. At the same time, the oral anti-diabetes drug market

boomed. According to Sidney Wolfe, head of Ralph Nader's health research group, American doctors wrote nearly 17 million prescriptions for the drugs in 1968. More than 50 percent of this market was captured by the Upjohn Company with its tolbutamide sold under the name Orinase. Thus the drug companies, and Upjohn in particular, had a great deal to lose if the anti-diabetes agents did not make a good showing in the clinical trial.

The first shock to the drug companies and to doctors who had been enthusiastically prescribing the oral drugs came in 1970. On 20 May, news was leaked to Wall Street that tolbutamide was to be withdrawn from the UGDP because it did not seem to be efficacious and because there was reason to suspect it caused cardiovascular complications. The reaction was immediate. The price of Upjohn's stock dropped dramatically and doctors switched patients from Orinase to Diabinese, a chemically similar drug made by Pfizer, Inc., or to DBI, the brand name for phenformin then made by Revlon, Inc.

The news from Wall Street puzzled the medical community. After all, tolbutamide was not a new drug and no one had ever before reported that it was toxic. Physicians with diabetic patients began to question the reasons for withdrawing the drug. The tolbutamide patients did not have a higher death rate than those in the other groups—they just had a higher proportion of deaths from cardiovascular causes. Physicians began to ask how the UGDP scientists determined the causes of death, and how the data were analyzed.

Despite these doubts about the validity of the UGDP's conclusions, the FDA, against the advice of its own advisory committee, acted swiftly on the study's results, even though it had not actually seen the UGDP data. Two days after the news about tolbutamide broke on the Dow-Jones ticker, the FDA endorsed the study's conclusions. Three days after that, the agency announced that warning labels

would be put on all oral anti-diabetes drugs. Yet the UGDP results still had neither been published nor presented to a scientific audience.

Three weeks later, the UGDP data were presented and debated at an American Diabetes Association (ADA) meeting at which time the ADA endorsed the study's conclusions. But the results were not to be published for another 6 months.

By the time of the ADA meeting, the debate over the UGDP was focused on the question of whether tolbutamide was toxic. The question intended to be answered by the UGDP—whether control of blood sugar prevents the complications of diabetes—was ignored. It turned out that it was never to be answered because, in most of the patients, blood-sugar levels had been poorly controlled.

As months went by after the news about tolbutamide was reported, questions about the UGDP became louder and more persistent. The FDA stuck by its original decision to put warning labels on the drug.

Soon the simmering discontent of some UGDP investigators about the conduct of the trial and its conclusions came to the surface. In November 1970, Bowen and Robert Reeves, who were UGDP investigators at the Seattle clinic, resigned from the study. They explained that 7 of the 20 UGDP investigators had disagreed with the decision to withdraw tolbutamide. (None of the others resigned.) But Max Miller of Case Western Reserve University, who was chairman of the UGDP, insisted that the decision to withdraw the drug be made to appear unanimous, arguing that otherwise the conclusion would not be accepted by the medical community.

This demand for a false show of unanimity disturbed Bowen and Reeves. They were already suspicious of Klimt because, they said, he had at first denied and then admitted that at the time the study began he had been a paid con-

sultant to U.S. Vitamin Pharmaceutical Corporation, a drug company with a stake in the trial's results, and had continued as a consultant until shortly before his appointment to the FDA. (Phenformin was originally sold by U.S. Vitamin. When tolbutamide was removed from the study, U.S. Vitamin more than quadrupled its sales of phenformin. Then U.S. Vitamin was taken over by Revlon.)

Klimt acknowledged to *Science* that he accepted $5000 from U.S. Vitamin during the years 1968 to 1970, but expressed astonishment that he could be accused of manipulating data for such a paltry sum.

Also in November of 1970, the CCD was formed by a group of 40 leading diabetologists who had decided to join forces in combating the UGDP. They retained a Boston lawyer named Neil Chayet, who specializes in medical-legal matters, to prevent the FDA from going ahead with its labeling proposal and to gain access to the UGDP's patient records. Chayet has, by a number of legal maneuvers, been able to delay implementation of the labeling requirement for the past 8 years.

The CCD still exists, now numbering about 250 diabetologists. (In contrast, about 2500 physicians are members of the ADA.) Its efforts have played a large role in keeping the UGDP controversy alive—so large a role that the study's supporters commonly preface their remarks about the CCD's arguments by saying that the members of the CCD, and Chayet in particular, are funded by Upjohn. Chayet has denied under oath that Upjohn has ever paid him for any work he did for the CCD.

Within the first year after tolbutamide was withdrawn from the UGDP the scene was set for the continuing dispute. Klimt's integrity was impugned, the CCD was formed, and the study's critics and supporters began to be polarized. But the study was not over. On 17 May 1971, nearly 1 year to the day after the tolbutamide story broke, news was leaked to Wall Street that phenformin too was to be withdrawn from the study. The UGDP data indicated that the diabetics taking phenformin suffered excess mortality from all causes. When reports of phenformin's imminent demise came over the Dow-Jones ticker, investors rushed to unload their Revlon stock. Revlon took a beating and was forced to stop trading on its stock that day.

When phenformin was withdrawn from the UGDP, the furor over the study and its conclusions knew no bounds. Supporters of the study were becoming increasingly strident. The debate had turned ugly, had turned into a duel in which the weapon of choice was the adhominem argument. Not only did the critics question Klimt's honesty, but the supporters accused the CCD and other critics of being drug company whores.

At least one critic of the UGDP was even warned that his criticisms and his associations with Upjohn might destroy his academic career. Stanley Schor, who at the time was head of the statistics department at Temple University, was paid by Upjohn to critique the UGDP. He says he quite honestly found faults in the study's design and analysis. Schor had much experience as a consultant, both for industry and for the government. "But this was the first time I ever agreed with a drug company and disagreed with the FDA," he says.

As a result of his role in criticizing the UGDP, Schor was accused of having been bought by Upjohn. He reports that a UGDP administrator said to him, "You have an outstanding scientific reputation. You'd better divorce yourself from these people ([the study's critics] or you'll be finished." Schor says that "a lot of peculiar things" happened after he criticized the study. He subsequently lost his consultantship at the FDA and left Temple University. He now works for Merck Sharp & Dohme.

The UGDP debate was largely limited to the United States. For example, Germany, which was just recovering

from the thalidomide tragedy, was greatly concerned that the drugs might be toxic. Shortly after tolbutamide was withdrawn, a meeting was held in Dusseldorf to discuss the UGDP. After hearing both sides of the debate, the German government decided that no action was required to restrict sales of the drug or warn doctors of its toxicity. The Canadian, British, and Swedish governments also considered the UGDP report no basis for action.

In what turned out to be a futile attempt to answer the persistent angry questions about the UGDP, Robert Q. Marston, who was then director of the NIH, asked that the Biometric Society, which is a professional society of statisticians, appoint a committee to review the UGDP. The committee was appointed in 1971. For 4 years it deliberated, talking to the study's critics, journeying to the coordinating center and various UGDP clinics, and considering other studies that did not support the UGDP's conclusions. Finally it published a report more or less vindicating the UGDP.

The Biometric Society report is a carefully worded document that defended clinical trials in general and answered some questions about the trial but nonetheless failed to satisfy the study's critics.

One of the most troublesome accusations about the UGDP which the Biometric Society committee considered is that the patients given tolbutamide had more risk factors for heart disease than patients given placebos. These are conditions such as high blood pressure and high concentrations of cholesterol in the blood, that increase the likelihood that a person will have heart disease. If these patients were at greater risk to begin with, the increased incidence of cardiovascular deaths in this group could reflect that fact and not the effects of tolbutamide.

In response to this criticism, the committee used a statistical model to decide how many cardiovascular deaths

would be expected in a population with the risk factors of the tolbutamide group. It determined that far fewer deaths would be expected than actually occurred.

A second problem involves data analysis. Critics object to the decision to consider each patient a member of the treatment group to which he was assigned, regardless of whether he adhered to that treatment. They point out that only 26 percent of the UGDP patients faithfully stayed with their originally assigned treatment.

In order to decide whether patients' lack of adherence to their assigned treatments altered the UGDP's results, the Biometric Society committee corrected for lack of adherence by two different statistical methods. Both methods yielded results that confirmed the original conclusion that tolbutamide causes excess cardiovascular deaths.

Still another often-cited criticism of the UGDP's findings is that there may have been some bias in assigning causes of death. As Alvan Feinstein of Yale University points out, many cases of cardiovascular disease are undetected during life and are only discovered at autopsy. Therefore, the more patients that are autopsied, the more likely it is that deaths will be assigned to cardiovascular causes. Fifty percent of the tolbutamide patients that died were autopsied as opposed to only 29 percent of the patients assigned to placebo or insulin. According to Feinstein, the statistical significance of the increased cardiovascular deaths in the tolbutamide group would vanish if only three deaths in each group were reassigned to different causes.

The Biometric Society conceded this point to the critics, saying that "some reservation about the conclusion that oral hypoglycemic agents are toxic must remain."

The Biometric Society report was published in the *Journal of the American Medical Association* along with an editorial by Thomas Chalmers, who is now dean of Mount Sinai Medical School and chairman of the UGDP advisory

committee. (He was then at NIH.) In his editorial, Chalmers estimated that the oral anti-diabetes drugs cause an additional 10,000 to 15,000 deaths each year in the United States. He obtained this estimate by interpreting literally the statistically insignificant trend toward more deaths in the UGDP patients taking tolbutamide. Even though his figures are controversial, Chalmers sticks by them.

While the arguments over the UGDP's design and data analysis were going on, the CCD had stalled the FDA by bringing to court the issue of whether the agency could put its intended warning label on *all* oral anti-diabetes drugs. The committee's argument was that any warning label should present both sides of the issue. It should reflect the controversy over the UGDP and take note of other studies that do not confirm the UGDP's conclusions. Lawyer Chayet contended that the FDA's own fair balance regulation required it to do this. The fair balance regulation was designed to prevent companies from making wild and extravagant claims for their products in package inserts without explaining serious differences of opinion and qualifications when they existed. When the First Circuit Court of Appeals in Boston sent the case back to the FDA asking that the two parties resolve their differences, the FDA modified its fair balance regulation as it applied to the government. Now only the drug companies, and not the FDA, must comply with the regulation.

The FDA tried again to put warning labels on the drugs, holding a hearing in August of 1975 to discuss its proposed labels. At the hearing, two sensational issues were brought up—one legal and the other personal. The legal issue may now be the subject of a Supreme Court case. The personal issue is the subject of an FBI investigation.

The legal question was brought up by Chayet. He attempted, on behalf of the CCD, to obtain the patient records from the UGDP. He explained that the committee's request to look at the raw data had "been shuttled from agency to

agency, ignored or denied." Finally, on 7 August 1975, Chayet received a letter from Theodore Cooper, then Assistant Secretary of HEW. Cooper wrote, "I have made further extensive inquiries of both the National Institutes of Health and the Food and Drug Administration. Neither agency has ever had the raw data in its possession."

Cooper went on to explain that the data apparently belong to Klimt. "I am informed," Cooper wrote, "that the raw data is [sic] now in the form of microfilm and is stored in a Maryland bank vault. . . . While I cannot, therefore, suggest it as a fruitful approach, it would appear that further efforts on your part should be directed to Dr. Klimt."

Chayet has as yet been unable to obtain the data from Klimt. Jerome Cornfield, a statistician at George Washington University who strongly defends the study, says it is only proper that Chayet be denied access to the UGDP data. The CCD, Cornfield explains, only wants to see the data to denigrate the study.

Nonetheless, Klimt explained to *Science* that it has always been his policy that the data should not be released until it had all been analyzed and the analyses published. Now that nearly all the UGDP reports are out, he says, the data are available. The only exceptions are the data pertaining to a monograph on insulin use, which is still being prepared.

Chayet maintains that all the data are not available. The patient records and the forms filled out at the clinics are still sequestered, he says. He says he is taking the issue of whether they should be available to the U.S. Supreme Court, explaining that he believes that in a government-funded study such as the UGDP in which major policy decisions hang on the data, it is inappropriate that neither NIH nor the FDA saw the data. (He says he has some qualms about whether all data from federally funded research should be publicly available, however, because if they are, researchers could be subject to harassment.)

The most inflammatory testimony at the 1975 hearing was Bowen's. She questioned the "personal integrity and scientific honesty" of Klimt, linking his consultantship at U.S. Vitamin to the UGDP's decision to withdraw tolbutamide. She explained that "it became increasingly difficult for investigators to voice legitimate scientific concerns in the semiannual meetings of the UGDP. The entire project sort of began to assume a vendetta-like quality against the manufacturers of tolbutamide."

Bowen's testimony stunned the audience at the FDA hearing and led the FDA to institute an audit of the beleaguered study. The audit results were recently made public. Once again the UGDP was vindicated and once again the critics remain unsatisfied.

At the time the audit was being conducted, FDA officials asked the Inspector General of HEW to look into Bowen's suspicions about Klimt. Chayet explains that, in early 1978, J. Richard Crout, who is head of the FDA's Bureau of Drugs, asked Bowen to come to the FDA and discuss her suspicions. Bowen came, bringing Chayet with her. Following his conversation with Bowen and Chayet, Crout allegedly took steps that resulted in HEW's investigation. (Crout refused to comment on this matter.)

In January 1979, the Inspector General turned the case over to the FBI. William Rhodes of the Baltimore office of the FBI will only say that the statute under which the agency claims jurisdiction is bribery and that it is investigating whether there is any substance to allegations involving Klimt and the UGDP.

Klimt protests that he is innocent and that the FBI investigation is just one more example of the harassment he has been subjected to for the past 8 years. He says he did not even know of the FBI's involvement until *Science* mentioned the matter.

Critics say that their qualms about the sequestered data are increased by some patient records that have recently been released. These records, previously held by Klimt, were turned over to the FDA when the agency was investigating a charge by Wolfe that phenformin is an imminent hazard to human health. As soon as it learned the FDA had these records, the CCD obtained them through a *Freedom of Information Act* request. Then Nathaniel Horowitz, a writer for the *Medical Tribune*, publicized the records in the newspaper. (The *Medical Tribune* had been running a series of articles critical of the UGDP.)

The study's critics were horrified by the evidence of patient mismanagement at the clinics, as revealed in the patient records. For example, some patients with malignant hypertension were untreated, a woman with a preexisting kidney failure and sickle cell anemia was given phenformin (the drug was specifically counter-indicated in her case), and a man with normal blood sugar was given insulin.

In addition to the patient mismanagement, the UGDP records reveal that data were frequently erroneously recorded. This sloppiness in treating patients and recording data is passed off by UGDP supporters who say that a few errors are inevitable in a study the size of the UGDP, and that it is necessary to consider the study as a whole. They point out that, according to the FDA audit, the errors and discrepancies in recording and analyzing data do not alter the UGDP conclusions.

Supporters of the UGDP commonly say that the study's critics are intellectually and emotionally unable to accept the fact that treatment of symptomless adult-onset diabetics does no good. Both Chalmers and Thaddeus Prout, a UGDP administrator from Johns Hopkins University, draw an analogy with a large-scale trial on treatment of high blood pressure that was conducted at about the same time as the UGDP. This study, directed by Edward Freis of the Veteran's Administration Hospital in Washington, D.C., pur-

portedly showed that anti-hypertension drugs prevent deaths and complications of hypertension. But, say Prout and Chalmers, Fries study was no better than the UGDP. Yet his study's results were immediately accepted and Freis won a Lasker Award.

The implication is that there is a widespread tendency in the clinical and research communities to accept findings that drugs are useful and to reject findings that drugs are useless. Freis, on the other hand, says his study is not at all comparable to the UGDP. It answered the original questions it was designed to answer and there was never any doubt about the statistical analysis and significance of its results.

Casting aspersions on the motives of the UGDP critics, however, cannot stem the increasing tide of objections to the study. Recently, Charles Edwards, the former FDA commissioner who accepted the first UGDP results and proposed the warning label, said that he made a mistake in listening to statisticians and not looking at the study's quality control. Edwards, who is now President of Scripps Clinic and Research Foundation, says, "The UGDP was a bad study. Why can't anyone admit that?"

On the other hand, Paul Meier of the University of Chicago, who was a member of the Biometric Society committee, says the UGDP is no worse than any other clinical trial. It's just that no one before had ever seen so much data from a trial. If Meier is correct, what does that say about clinical trials in general? Should their quality control be improved and, if so, how? How much money, time, and resources should be devoted to them?

The FDA has not yet given up its battle to put warning labels on all oral anti-diabetes drugs. It recently proposed a label and planned to accept comments until 15 January 1979. Now, at the request of the ADA, which recently took back its original endorsement of the study's conclusions, the FDA extended its comment period until 15 March. But

the warning section of its proposed label still does not reflect the scientific controversy. Perhaps, as Edwards says, this is an issue in which the FDA should not intervene, should not try to decide in the face of such a dispute whether the UGDP's conclusions are valid.

It has been rumored that the FDA may compromise on its warning label by restricting the warning to tolbutamide. Prout believes such a restriction would be a sellout because it would allow drug companies to profitably market their new anti-diabetes drugs in this country. However, Edwards and others point out that it is hard to justify extending the warning to all anti-diabetes drugs. Even Klimt says he could not scientifically justify such an extension. ("It's not my fault if the FDA over-interpreted our data," he told *Science*.)

Some medical scientists think that the UGDP battle is winding down—that the ADA's change of mind about the study means it is discredited by all but its most strident supporters. They note that now the American Medical Association says it is reassessing its position in support of the UGDP and that the comments received by the FDA on its warning label proposal are overwhelmingly critical of the UGDP. Of course, the debate will not end until the warning label controversy is resolved. This will be the final decision in a fight that, like a bad boxing match, has no sharp punches, no telling blows, no display of finesse—just a lot of clinching, shouting, glancing punches and, finally, desultory pats.

—Gina Bari Kolata

UNIVERSITY OF MARYLAND
SCHOOL OF MEDICINE
INSTITUTE OF INTERNAL MEDICINE
BALTIMORE, MARYLAND 21201

DIVISION OF EPIDEMIOLOGY AND BIOSTATISTICS

December 16, 1970

Shirley Weisenfeld, M.D.
The Jewish Hospital and Medical
Center of Brooklyn
555 Prospect Place
Brooklyn, New York 11238

Dear Shirley:

Thank you for your letter of December 7 which brings out into the open a question I have discussed previously with Dr. Goldner.

Acceptance of a one-year assignment as Director of the Office of Scientific Coordination of the Food and Drug Administration on my part was purely motivated by the need to assist this important organization in its scientific problems. My position in the FDA has nothing whatsoever to do with the regulatory duties of the organization nor of the review of INDs (investigational drug licenses) and NDAs (marketing permissions for new drugs). Furthermore, I have been specifically excluded from consideration of diabetes and hypolipemic matters by the Director of the Bureau of Drugs. Thus, in no way is there any conflict of interest between my position in the UGDP and my temporary position with the FDA.

As I have told you, my position with the FDA will terminate September 30, 1971. Until this time I am spending twenty percent of my time in Baltimore to take care of my responsibilities with regard to the UGDP and the CDP.

Like you, Shirley, and many others I have spent a good part of the last ten years helping with the UGDP in its many aspects. I do not think that I ought to withdraw from such a function now nor do I feel it is fair to ask me to jeopardize my scientific involvement. I would therefore have to reject your suggestion that I resign from the UGDP because of the simple appearance and not the fact of a conflict of interest since I am temporarily with the FDA.

Hoping that this letter will have clarified the situation and allayed your fears, I remain as always

Cordially yours,

/s/ CHRISTIAN R. KLIMT
Christian R. Klimt, M.D., Dr. P.H.
Professor and Director

cc: All UGDP Investigators

CRK:meb

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

July 13, 1976

Dr. Christian Klimt
Division of Clinical Investigation
School of Medicine
University of Maryland
600 Windhurst Avenue
Baltimore, Maryland 21201

Dear Dr. Klimt:

This letter is to advise you that the Food and Drug Administration, with the authorization of the National Institute of Arthritis, Metabolism, and Digestive Diseases, will conduct an audit of the UGDP study. NIAMDD hereby designates FDA to conduct the audit and exercise all authority granted to NIAMDD under 45 CFR, part 74.

Sincerely yours,

/s/ G. DONALD WHEDON
G. Donald Whedon, M.D.
Director
National Institute of Arthritis,
Metabolism, and Digestive Diseases

cc
Mr. Stuart Pape
Office of the General Counsel
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

February 9, 1977

In reply refer to F77-1128

Neil L. Chayet
Chayet and Sonnenreich, P.C.
6 Fayette Street
Boston, Massachusetts 02116

Dear Mr. Chayet:

In response to your letter of January 5, 1977 we will release upon receipt of $39.10 as detailed on the enclosed invoice:

1) copies of all documents copied at the UGDP Coordinating Center during the course of our audit,
2) a copy of a computer print-out provided us by the Coordinating Center,
3) copies of all available baseline electrocardiograms on subjects who died during the course of the UGDP study, and
4) copies of pertinent portions of the death record of a subject identified as FDA audit #71 obtained from the UGDP Death Committee records at Massachusetts General Hospital.

The above constitute all the UGDP documents that have come into our possession to date during the course of the UGDP audit. If these documents are not as informative as you might like, it is because most of our audit was per-

formed by abstracting data from UGDP records rather than by making copies of voluminous available records. Data obtained are currently being evaluated. A report of our findings will be available as soon as that evaluation is completed.

Our audit is being conducted by Dr. Alan Lisook of the Bureau of Drugs' Scientific Investigations Staff in conjunction with another physician, statisticians, and personnel of our field staff. It is still in progress. Past visits to the Coordinating Center were made on 8/6 and 8/18 and 9/15 through 10/14/76. A visit was made to Massachusetts General Hospital to review Death Committee records from 9/29 through 10/01/76.

Sincerely yours,

/s/ J. Richard Crout, M.D.
J. Richard Crout, M.D.
Director
Bureau of Drugs

Enclosure

CHAYET AND SONNENREICH, P.C.

Attorneys at Law
6 Fayette Street
Boston, Massachusetts 02116

(617) 357-0202

May 5, 1977

Honorable Donald Kennedy, Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Dr. Kennedy:

It has come to our attention that an audit conducted by the Food and Drug Administration regarding the UGDP raw data is now complete. It has further come to our attention that the conclusions of the audit will be made public by the Food and Drug Administration at the early June meeting of the American Diabetes Association.

Please note that on January 5, 1977, request was made on behalf of the Committee for the Care of the Diabetic for all materials gathered by the FDA during the course of the UGDP audit. This request followed specific assurances of the availability of such materials by the Department of Justice speaking on behalf of the Food and Drug Administration during oral argument of the Freedom of Information action brought by the Committee for the Care of the Diabetic (*Forsham v. Califano,* United States Court of Appeals, D.C. Circuit, C.A. 76-1308). On February 9, Dr. Crout responded to our request stating that the materials would be released upon payment of $39.10 for the costs of reproduction. Despite our having made the requested payment on March 24, 1977 (Check No. 224), we have still not received any of the requested materials.

To release the results of the UGDP audit at a meeting which will receive broad coverage by the lay press and without having made the audit materials available to the Committee for the Care of the Diabetic for *prior* scientific analysis and comment will be to assure a repetition of events of six years ago when diabetic patients first read about the UGDP in the newspapers. Their physicians were unable to explain the meaning of the study, not having seen or had an opportunity to review the data in advance. Such a course of action by the FDA would again be detrimental to the health and welfare of the hundreds of thousands of diabetic patients throughout the United States.

Therefore, on behalf of the Committee for the Care of the Diabetic and pursuant to the Freedom of Information Act, 5 USC § 552 and regulations promulgated thereunder, request is hereby again made for all materials, including the raw data and any abstracts thereof, that were gathered as a result of the UGDP audit. It is requested that such materials be forwarded to the Committee for the Care of the Diabetic as soon as possible.

Very truly yours,

Neil L. Chayet

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

May 20, 1977

Our Ref: F77-1,128

Mr. Neil L. Chayet
Chayet and Sonnenreich, P.C.
Attorneys at Law
6 Fayette Street
Boston, MA 02116

Dear Mr. Chayet:

This is in reply to your May 5, 1977 letter to Dr. Kennedy concerning your request for all materials gathered by FDA during the course of the UGDP audit.

Our Accounting Operations Branch states they have no record of receiving your check No. 224 for $39.10 in payment for this material.

However, we are enclosing the requested records. Please send us a copy of your cancelled check so that we may clear our records.

As you will note, minor deletions of material have been made in the records furnished to you. In the judgment of the Food and Drug Administration the information deleted does not fall within the scope of your request and, in any case, is not required to be disclosed under the Freedom of Information Act. If, however, you do desire to review the deleted material, please make an additional request. If the agency should then deny you this information, you would have the right to appeal such denial to the Department of

Health, Education, and Welfare. Any letter of denial will tell you how to make this appeal.

Incidentally, your sources of information regarding the ADA meeting are incorrect. FDA has no plans to make the conclusions of our audit of the UGDP data public prior to their publication in the Federal Register.

Sincerely yours,

/s/ MARK A. ELENGOLD
Mark A. Elengold
Freedom of Information Officer
Bureau of Drugs (HFD-35)

5 U.S.C. § 552

Title 5

Government Organization and Employees

CHAPTER 5—ADMINISTRATIVE PROCEDURE

Part I—The Agencies Generally

SUBCHAPTER II—ADMINISTRATIVE PROCEDURE

§ 552. Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public—

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general

policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying—

(A) final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register; and

(C) administrative staff manuals and instructions to staff that affect a member of the public;

unless the materials are promptly published and copies offered for sale. To the extent required to prevent a clearly unwarranted invasion of personal privacy, an agency may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, or staff manual or instruction. However, in each case the justification for the deletion shall be explained fully in writing. Each agency shall also maintain and make available for public inspection and copying current indexes providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967,

and required by this paragraph to be made available or published. Each agency shall promptly publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of each index or supplements thereto unless it determines by order published in the Federal Register that the publication would be unnecessary and impracticable, in which case the agency shall nonetheless provide copies of such index on request at a cost not to exceed the direct cost of duplication. A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if—

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

(3) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, each agency, upon any request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

(4)(A) In order to carry out the provisions of this section, each agency shall promulgate regulations, pursuant to notice and receipt of public comment, specifying a uniform schedule of fees applicable to all constituent units of such agency. Such fees shall be limited to reasonable standard charges for document search and duplication. Documents shall be furnished without charge or at a reduced charge where the agency determines that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter de novo, and may examine the contents of such agency records in camera to determine whether such records or any part thereof shall be withheld under any of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action.

(C) Notwithstanding any other provision of law, the defendant shall serve an answer to otherwise plead to any complaint made under this subsection within thirty days after service upon the defendant of the pleading in which such complaint is made, unless the court otherwise directs for good cause shown.

(D) Except as to cases the court considers of greater importance, proceedings before the district court, as authorized by this subsection, and appeals therefrom, take precedence on the docket over all cases and shall be assigned for hearing and trial or for argument at the earliest practicable date and expedited in every way.

(E) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.

(F) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the

withholding, the Civil Service Commission shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Commission, after investigation and consideration of the evidence submitted, shall submit its findings and recommendations to the administrative authority of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Commission recommends.

(G) In the event of noncompliance with the order of the court, the district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

(5) Each agency having more than one member shall maintain and make available for public inspection a record of the final votes of each member in every agency proceeding.

(6)(A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall--

(i) determine within ten days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination; and

(ii) make a determination with respect to any appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection.

(B) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the reasons for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days. As used in this subparagraph, "unusual circumstances" means, but only to the extent reasonably necessary to the proper processing of the particular request—

(i) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(ii) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(iii) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

(C) Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request. Any notification of denial of any request for

records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such request.

(b) This section does not apply to matters that are—

(1)(A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the

case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection.

(c) This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress.

(d) On or before March 1 of each calendar year, each agency shall submit a report covering the preceding calendar year to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress. The report shall include—

(1) the number of determinations made by such agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;

(2) the number of appeals made by persons under subsection (a)(6), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information;

(3) the names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each;

(4) the results of each proceeding conducted pursuant to subsection (a)(4)(F), including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;

(5) a copy of every rule made by such agency regarding this section;

(6) a copy of the fee schedule and the total amount of fees collected by the agency for making records available under this section; and

(7) such other information as indicates efforts to administer fully this section.

The Attorney General shall submit an annual report on or before March 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subsections (a)(4)(E), (F), and (G). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.

(e) For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 383; Pub.L. 90-23, § 1, June 5, 1967, 81 Stat. 54; Pub.L. 93-502, §§ 1-3, Nov. 21, 1974, 88 Stat. 1561-1564; Pub.L. 94-409, § 5(b), Sept. 13, 1976, 90 Stat. 1247.

HEW Regulations Governing Administration of Grant Research

Title 45—Public Welfare

Subtitle A—Department of Health, Education, and Welfare

Part 6—Inventions and Patents (General)

§ 6.1 Publication or patenting of inventions.

It is the general policy of the Department that the results of Department research should be made widely, promptly and freely available to other research workers and to the public. This availability can generally be adequately preserved by the dedication of a Government-owned invention to the public. Determinations to file a domestic patent application on inventions in which the Department has an interest will be made where the circumstances indicate that this is desirable in the public interest, and if it is practicable to do so. Department determinations not to apply for a domestic patent on employee inventions are subject to review and approval by the Commissioner of Patents. Except where deemed necessary for protecting the patent claim, the fact that a patent application has been or may be filed will not require any departure from normal policy regarding the dissemination of the results of Department research.

[23 FR 2990, Mar. 27, 1963. Redesignated at 31 FR 12842, Oct 1, 1966]

Part 8—Inventions Resulting From Research Grants, Fellowship Awards, and Contracts For Research

§ 8.0 Policy.

(a) The Department of Health, Education, and Welfare each year is expending large sums in the form of grants for research. These grants are made primarily by the Public Health Service in carrying out its broad responsibility under the Public Health Service Act to promote and coordinate research in the field of health and to make available information concerning such research and its practical application. The scientific and technological advances attributable, in varying degrees to this expenditure of public funds frequently include patentable inventions.

(b) The Department, as a matter of policy, takes the position that the results of research supported by grants of public moneys should be utilized in the manner which would best serve the public interest. It is believed that the public interest will in general be best served if inventive advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public.

(c) On the other hand, in some cases it may be advisable to permit a utilization of the patent process in order to foster an adequate commercial development to make a new invention widely available. Moreover, it is recognized that inventions frequently arise in the course of research activities which also receive substantial support from other sources, as well as from the Federal grant. It would not be consistent with the cooperative nature of such activities to attribute a particular invention primarily to support received from any one source. In all these cases the Department has a responsibility to see that the public use of the

fruits of the research will not be unduly restricted or denied.

(d) The following conditions have been adopted to govern the treatment of inventions made in these various types of situations. They are designed to afford suitable protection to the public interest while giving appropriate recognition to the legitimate interests of others who have contributed to the invention.

§ 8.1 Conditions to be included in research grants.

Subject to legislative directives or Executive orders providing otherwise, all grants in aid of research shall provide as a condition that any invention arising out of the activities assisted by the grant shall be promptly and fully reported, and shall provide either

(a) That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the Assistant Secretary (Health and Scientific Affairs) or

(b) That the ownership and disposition of all domestic rights shall be left for determination by the grantee institution in accordance with the grantee's established policies and procedures, with such modifications as may be agreed upon and specified in the grant, provided the Assistant Secretary (Health and Scientific Affairs) finds that these are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties, and provided the Government shall receive a royalty-free license, with a right to issue sublicenses as provided in § 8.3, under any patent applied for or obtained upon the invention.

(c) Wherever practicable, any arrangement with the grantee pursuant to paragraph (b) of this section shall provide in accordance with Executive Order 9865 that there be reserved to the Government an option, for a period to be

prescribed, to file foreign patent applications upon the invention.

[20 FR 6749, Sept. 14, 1965, as amended at 31 FR 12842, Oct. 1, 1966]

Part 74—Administration of Grants

Subpart D—Retention and Custodial Requirements for Records

§ 74.20 Length of retention period.

HEW will not impose record retention requirements over and above those established by the grantee except that financial records, supporting documents, statistical records, and all other records pertinent to an HEW grant shall be retained for a period of three years. This requirement applies to the pertinent records and documents of grantees, subgrantees, and recipients under grants or subgrants of negotiated contracts (or subcontracts) exceeding $10,000. The requirement is qualified as follows:

(a) If audit by or on behalf of the Federal Government has begun but is not completed at the end of the three-year period, or if audit findings have not been resolved at the end of the three-year period, the records shall be retained until resolution of the audit findings. In no case, however, will HEW require retention of records relating to any grant with respect to which actions by the United States to recover for diversion of money paid under the grant are barred by the statute of limitations in 28 U.S.C. 2451(b).

(b) In order to avoid duplicate recordkeeping, granting agencies may make special arrangements with grantees to retain any records which are continuously needed for joint use. The granting agency will request transfer of records to its custody from grantees when it determines that the records possess long-term retention value. When the rec-

ords are transferred to or maintained by HEW, the three year retention requirement is not applicable to the grantee.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44552, Oct. 8, 1976]

§ 74.23 Access to records.

(a) HEW and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the grantee which any of them determine are pertinent to a specific HEW grant, for the purpose of making audit; examination, excerpts and transcripts.

(b) In the case of a subgrant (or negotiated contract or subcontract exceeding $10,000) under a HEW grant, the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the subgrantee (or contractor or subcontractor) which the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the subgrantee or contractor or subcontractor) which the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives determine are pertinent to the specific HEW grant, for the purpose of making audit, examination, and transcripts.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44552, Oct. 8, 1976]

§ 74.24 Restrictions on public access.

Unless otherwise required by law, HEW will not place restrictions on grantees which will limit public access to the grantee's records or to the records of their subgrantees

or contractors, except when the records must remain confidential for any of the following reasons:

(a) To prevent a clearly unwarranted invasion of personal privacy;

(b) To comply with an executive order or statute which specifically requires the records to be kept secret; or

(c) To protect commercial or financial information obtained from a person or firm on a privileged or confidential basis.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44553, Oct. 8, 1976]

Pertinent FDA Regulations Governing Maintenance of Records and Disclosure of Data

Chapter I—Food and Drug Administration

§ 12.85 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published pursuant to § 12.35, the director of the bureau responsible for the matters involved in the hearing shall submit to the Hearing Clerk:

(1) The relevant portions of the administrative record of the proceeding up to that time. Those portions of the administrative record of the proceeding which are not relevant to the issues to be considered at the public hearing shall not be placed on public display and shall not be part of the administrative record of that proceeding.

(2) All documents in his files containing factual data and information, whether favorable or unfavorable to his position, which relate to the issues involved in the hearing.

(3) All other documentary data and information on which he relies.

(4) A narrative statement of his position on the factual issues stated in the notice of hearing and the type of evidence he intends to introduce in the hearing in support of his position.

(5) A signed statement that, to the best of his knowledge and belief, the submission complies with the requirements of this section.

(b) Within 60 days after the notice of hearing is published in the FEDERAL REGISTER pursuant to § 12.35, or, where no participant will be prejudiced, within such shorter or longer period of time as the presiding officer orders, each

participant shall submit to the Hearing Clerk all data and information specified in paragraph (a) (2) through (5) of this section, and any objections with respect to the completeness of the administrative record filed pursuant to paragraph (a) (1) of this section.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen at that time.

(d) The failure to comply with the provisions of this section in the case of a participant shall constitute a waiver of the right to participate further in the hearing and in the case of a party shall also constitute a waiver of the right to a hearing.

(e) Any documentary data and information submitted by one participant may be referenced by another. Participants are encouraged to exchange and consolidate lists of documentary evidence prior to reproducing it for submission to the Hearing Clerk in order to reduce duplicative submissions. If a particular document is bulky or is in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, a participant may request the presiding officer for permission to submit a reduced number of copies to the Hearing Clerk.

(f) The presiding officer shall rule on questions relating to this section.

§ 20.62 Inter- or intra-agency memoranda or letters.

All communications within the Executive Branch of the Federal government which are in written form or which are subsequently reduced to writing may be withheld from public disclosure except that factual information which is reasonably segregable in accordance with the rule established in § 20.22 is available for public disclosure.

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§ 20.64 Investigatory records compiled for law enforcement purposes.

(c) Any investigatory record which is disclosed to any person, including any person who is the subject of a Food and Drug Administration investigation, and any data or information received from any person who is the subject of a Food and Drug Administration investigation relating to such investigation, is available for public disclosure at that time in accordance with the rule established in § 20.21, except that:

(1) Disclosure of such records shall be subject to the other exemptions established in this subpart and to the limitations on exemptions established in Subpart E of this part.

(2) The record of a section 305 hearing shall be available for public disclosure only in accordance with the provisions of § 7.87 of this chapter.

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§ 20.81 Data and information previously disclosed to the public.

(a) Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to Subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member

of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy.

(1) For purposes of this section, an individual shall be deemed to be a consultant only if disclosure of the information was necessary in order to perform that specific consulting service and the purpose of the disclosure was solely to obtain that service. The number of consultants who have received such information shall have been limited to the number reasonably needed to perform that particular consulting service.

(2) For purposes of this section, other commercial arrangements shall include licenses, contracts, and similar legal relationships between business associates.

(3) For purposes of this section, data and information disclosed to clinical investigators or members of institutional review committees, whether required by § 312.1(a)(3) of this chapter or other regulations of the Food and Drug Administration, or made voluntarily, if accompanied by appropriate safeguards to assure secrecy and otherwise in accordance with this section, are not deemed to have been previously disclosed to any member of the public within the meaning of paragraph (a) of this section.

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Part 20—Public Information

Subpart F—Availability of Specific Categories of Records

§ 20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.

(a) Any list that may be prepared by the Food and Drug Administration of testing and research being conducted by or with funds provided by the Food and Drug Administration is available for public disclosure.

(b) Any contract relating to agency testing and research, and any progress report relating thereto, is available for public disclosure.

(c) The results of all testing or research conducted by or with funds provided by the Food and Drug Administration, such as toxicological testing, compliance assays, methodology studies, and product testing, are available for public disclosure when the final report is complete and accepted by the responsible Food and Drug Administration official, after deletion of any information that would reveal confidential investigative techniques and procedures, e.g., the use of "markers" to document adulteration of a product. If such results are disclosed in an authorized manner to any member of the public before the final report is available, they are immediately available for public disclosure to any member of the public who requests them.

(d) Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed.

Title 21—Food and Drugs

Chapter I—Food and Drug Administration

Part 312—New Drugs For Investigational Use

Subpart A—Exemptions From Section 505(a)

§ 312.1 Conditions for exemption of new drugs for investigational use.

(a) A shipment or other delivery of a new drug shall be exempt from section 505(a) of the act if all the following conditions are met:

• • •

(4) The sponsor maintains adequate records showing the investigator to whom shipped, date, quantity, and batch or code mark of each such shipment and delivery, until 2 years after a new-drug application is approved for the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration has been so notified. Upon the request of a scientifically trained and properly authorized employee of the Department at reasonable times, the sponsor makes the records referred to in this subparagraph and in paragraph (a)(2) of this section available for inspection, and upon written requests submits such records or copies of them to the Food and Drug Administration. If the investigational drug is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970 adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

• • •

(13) The sponsor shall obtain from each investigator involved in clinical trials a signed statement in the following form:

Form FD-1573

Department of Health, Education, and Welfare, Food and Drug Administration

Statement of Investigator

• • •

4. The undersigned understands that the following conditions, generally applicable to new drugs for investigational use, govern his receipts and use of this investigational drug:

• • •

e. The investigator shall maintain the records of disposition of the drug and the case histories described above for a period of 2 years following the date a new drug applications is approved for the drug; or if the application is not approved, until 2 years after the investigation is discontinued. Upon the request of a scientifically trained and properly authorized employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying. The subjects' names need not be divulged unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual cases studied, or do not represent actual results obtained.